Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals

ARMS#

13127

2 - LABEL SAMPLE

000001

The following Dietary Supplements/Prescription Medications were taken by [redacted] within the past year:

PRESCRIPTION MEDICATONS:

1. Cerenex Pharmaceuticals...Imitrex...Sumatriptan Succinate Tablets

THE FOLLOWING ARE HOMEOPATHIC DIETARY SUPPLEMENTS:

1. Aura Cacia...Lavender..Essential Oil
2. Gaia Herbs...Melissa Supreme...Alcohol Free Plant Extract
3. Herb Pharm...Blue Cohosh...Root & Rhizome Concentrated Herbal Drops...Caulophyllum thalictroldes
4. Herb Pharm...Black Cohosh...Root & Rhizome Concentrated Herbal Drops...Cimicifuga racemosa
5. Wyndmere...Chamomile Roman...Pure Essential Oil
6. Green Mountain Herbs...Oatstraw...Extract
7. Bach...Rescue Remedy...Flower Essence
8. Herb Shop...Lobelia...Tincture
9. Gaia Herbs...Fresh Lobelia Herb & Seed...Plant Extract
10. Gaia Herb...Milk Thistle Seed...Herbal Extract
11. Gaia Herbs...Lobelia Herb & Mature Seed...Concentrated Herbal Drops
12. Herb Pharm...Motherwort Flowering Tops...Concentrated Herbal Drops
13. Gaia Herbs...Fresh St. Johnswort Flower Buds...Plant Extract
14. Herb Pharm...Dandelion...Fresh Root, Leaf & Flower...Liquid Herbal Extract
15. A. Vogel...Nephrosolid K.B. Complex...Herbal Dietary Supplement
16. Rainbow Light...Children's Relax...Custom Herbal Extracts
17. Gaia Herbs...Phyto Proz Supreme...A Liquid Herbal Blend for Emotional Balance...A Dietary Supplement
18. False Unicorn...New Moon Extract...Herbal Food Formulae
19. Gaia Herbs...Skullcap
20. Herb Pharm...Skullcap Compound...Concentrated Herbal Drops
21. Bioron...Eupatorium perfoliatum...Homeopathic Medicated Pellets
22. Bioron...Carbo Vegetabilis...Homeopathic Medicated Pellets
23. Bioron...Arnica Montana...Homeopathic Medicated Pellets
24. Pure Life...Vitamin E-200 I.U....d-alpha tocopherol
25. Nature's Bounty...Chondroitin Complex with Glucosamine
26. Ginseng Tablets
27. Now...Plant Enzymes...with Lactase, Protease, Papain, and Bromelain...A Dietary Supplement
28. Klamath...Blue Green Algae...Whole Food Freeze Dried Powder
29. Country Life...Natural...Lecithin...1200 mg.
30. Herbal Harvest...from Nature's Bounty...Black Cohosh...Natural Herbal Supplement
31. Montana Big Sky...Bee Pollen Royal Jelly & Propolis Capsules
32. Earthrise...Spirulina...Blue-Green Algae

33. ThinTab 100...Stimulates Weight Loss...Thermogenic...Burns Body Fat...Pure Herb Supplement
34. Nature's Way...European Select...Red Raspberry Leaves
35. Solaray...Grapenol...Dietary Supplement...100% Grape Seed Extract
36. Herbal Harvest...St. John's Wort...Standardized Extract...Natural Herbal Supplement
37. Light Force...Magical...Calcium, Minerals & Trace Elements with Spirulina
38. Light Force...Exta-Cee...Spirulina and Ester-C with Flanagan Microclusters
39. Earthrise...Clean Health...Internal Cleanse...Advanced Multi-Fiber & Herbal Dietary Supplement
40. Nature Wealth...DHEA...Dehydroepiandrosterone
41. Mega Food...Foodstate Nutrition...Antioxidant...DailyFoods Formula...Dietary Supplement
42. Nature's Bounty...Natural...Glucosamine Sulfate
43. Nature's Way...Kelp...Sea Harvested
44. Nature's Way...Wild American...Scullcap Herb...Herbal Dietary Supplement
45. Light Force...Digestable...Enzymatic Dietary Supplement with Flanagan Microclusters
46. Bread & Circus...Pro-90 Blend...Powder
47. Super Green Pro 96...Soy Protein...High Protein Energy with Super Whole Foods Complex
48. Seasilver...Foundation Health Program
49. Rejuvex...For Women...During and After Menopause
50. Nature's Bounty...Natural...Melatonin
51. Herbal Harvest...Ginkgo Biloba Extract...Natural Herbal Supplement
52. Nature's Way...Certified Organically Grown...Red Clover...Blossom and Herb
53. Nature's Secret...Multi-Herb...Herbal Dietary Supplement...With Herbalgest
54. Nature's Way...A Dr. John R. Christopher Formula...Rheum-Aid...Herbal Food Formula
55. Nature's Way...Certified Organically Grown...Alfalfa Leaves...Herbal Dietary Supplement
56. Nature's Way...Certified Organically Grown...Nettle Herb...Herbal Dietary Supplement
57. Nature's Bounty...Natural...Glucosamine Sulfate
58. Nature's Way...A. Dr. John R. Christopher Formula...Change-O-Life...Herbal Food Formula
59. Nature's Bounty...Super Antioxidant Formula
60. Rainbow Light...Positive Menstrual Support...Nutrients, Herbs & Superfoods featuring Cramp Bark, Dong Quai & Red Raspberry
61. Aura Cacia...Sage...Salvia Officinalis...Essential Oil
62. GNC...Biotin
63. Ginsana...100mg Standardized...G115 Ginseng Conc....FA87949A EXP DEC 2000
64. Echinacea...HerbalGelExtracts...LOT 68902 EXP 10/98
65. Ginkgo Biloba...HerbalSureExtracts
66. Earthrise...Chlorella...A Green Micro Algae
67. Ginseng...EXP 3/01...LOT 41032

68. GNC...beta-Carotene...Vitamin A Source
69. Eclectic Institute...Fresh Freeze-Dried...Nettles Leaf
70. Nature's Way...German Chamomile Flowers
71. Nature's Way...Wild European Dandelion Root
72. Nature's Way...Wild American Golden Seal Root
73. Nature's Way...European Select Red Raspberry Leaves
74. Nature's Way...Wild American Scullcap Herb
75. Nature's Way...Certified Organically Grown...Echinacea Herb
76. Futurebiotics...Bromelain...Pineapple Digestive Enzyme
77. Nature's Secret...Multi-Fiber...Herbal Dietary Supplement...With Herbalgest
78. Nature's Way...Chinese Ginger Root
79. Nature's Way...Certified Organically Grown...Blessed Thistle Herb
80. Nature's Way...Wild American Golden Seal Root
81. Nature's Way...Wild American White Oak Bark

♦ **NOTE:** Indicates supplements reportedly being taken by [redacted] most recently. According to Mr. [redacted] his wife recently visited an island in [redacted] over the summer where she purchased these items.

The following are other prescription medications that [redacted] was taking. Actual bottles were confiscated by the [redacted] Police, then turned over to the medical examiner:

1. Depakote
2. Prozac
   (According to Mr. [redacted], Number 1 & 2 were being taken in combination to treat Bipolar Disorder)
3. Antibiotic (name unknown) - taken prior to dental procedures

Food and Drug Administration Office of Regulatory Affairs

Collection Report

For Sample Number: 39234

Flag	Flag Remarks

Episode Number	Origin	Basis	Sample Type	FIS Smpl Num	Status
	Domestic	Surveillance	Documentary	99915918	Completed

FEI	Date Collected	Product Code	Responsible Firm	PAC	Hours
	04-DEC-98	54YYY99	Dealer	46R801	70

Related Smpl Num	Position Class	Sampling District	NDC Number	Permit Number	Storage Rqrmnt.
	INS	NWE-DO			Ambient

Dealer is Consumer	Crx/DEA Schedule	Recall Num	Consumer Compl. Num	Brand Name
Yes				

Product Description
Various Homeopathic Remedies

Product Label

Reason for Collection | **MFG Codes** | **Expiration Date**
Medwatch Assignment Project #13127

Firm Legal Name	Address	Type of Firm	Firm FEI	FCE

Size of Lot	Est. Value	Rcpt Type	Date Shipped & Doc. Ref.
unknown	$1,000	None	

Description of Sample
Copies of labeling with handwritten descriptions

Method of Collection
Collected original bottles, copied and mounted labels onto paper with handwritten descriptions

How Prepared
Collected original bottles, copied and mounted photocopied labels onto paper with handwritten descriptions for preparation to be mailed to Bridgette Wallace, CFSAN

Collector's Identification on Package and/or Label	Collector's Identification on Seal
N/A	N/A

Sample Delivered To	Date Delivered	Orig C/R & Records To
CFSAN	12/04/1998	NWE-DO
	Lab w/Split Sample	**Lab**
	0	CFSAN-LABS

Document Number	Document Date	Document Type	Document Remarks

Remarks
See attached list and copies of labeling

Payment Amount	Payment Method	704(d) Sample	702(b) Portion	Collector's Name
$0.00	Borrowed	No	No	Kathleen A Sousa

Name of Signer	Date & Time of Signature		Meaning
Kathleen A Sousa	12/30/1998	09:06 AM	Collector

000005

Imitrex®
(sumatriptan
succinate)
Tablets
25 mg sumatriptan
Glaxo Inc., RTP, NC 27709
LOT 7ZP1190
EXP AUG 00

PEEL

Imitrex®
(sumatriptan
succinate)
Tablets
25 mg sumatriptan
Glaxo Inc., RTP, NC 27709
LOT 7ZP1190
EXP AUG 00

PEEL

Imitrex®
(sumatriptan
succinate)
Tablets
25 mg sumatriptan
Glaxo Inc., RTP, NC 27709
LOT 7ZP1190
EXP AUG 00

PEEL

NDC 0173-0460-02

CERENEX
PHARMACEUTICALS

Imitrex®
(sumatriptan succinate)
Tablets

25 mg sumatriptan

Each tablet contains sumatriptan succinate equivalent to 25 mg of sumatriptan.

Store between 2° and 30°C (36° and 86°F).

Caution: Federal law prohibits dispensing without prescription.

9 Tablets

Imitrex®
(sumatriptan succinate)
Tablets
25 mg sumatriptan

N 3 0173-0460-02 8

C 0173-0460-02

4054587
000536

LOT 7ZP1190
EXP AUG 00

(1)
"Imitrex" - Prescription medication being taken by [redacted] for migraines

6

Imitrex®
(sumatriptan succinate)
Tablets
25 mg sumatriptan

CERENEX
PHARMACEUTICALS

Imitrex®
(sumatriptan succinate)
Tablets
25 mg sumatriptan

[redacted]
Dr. [redacted]
04/24/98
TAKE 1 TABLET AS NEEDED FOR MIGRAINE

9TAB

IMITREX 25MG TABLET
REFILL (5) DISCARD AFTER 04/24/99

000006

Cerenex Pharmaceuticals
Division of Glaxo Inc
Research Triangle Park, NC 27709

[redacted]

Best Quality FDA

Information for the Consumer
Imitrex® (sumatriptan succinate) Tablets

Please read this leaflet carefully before you take Imitrex Tablets. This provides a summary of the information available on your medicine. Please do not throw away this leaflet until you have finished your medicine. You may need to read this leaflet again. This leaflet does not contain all the information on Imitrex Tablets. For further information or advice, ask your doctor or pharmacist.

Information About Your Medicine:

The name of your medicine is Imitrex (sumatriptan succinate) Tablets. It can be obtained only by prescription from your doctor. The decision to use Imitrex Tablets is one that you and your doctor should make jointly, taking into account your individual preferences and medical circumstances. If you have risk factors for heart disease (such as high blood pressure, high cholesterol, obesity, diabetes, smoking, strong family history of heart disease, or you are postmenopausal or a male over 40), you should tell your doctor, who should evaluate you for heart disease in order to determine if Imitrex is appropriate for you. Although the vast majority of those who have taken Imitrex have not experienced any significant side effects, some individuals have experienced problems and, [illegible] considering the extensiveness of Imitrex use worldwide, [illegible] reported. In all but a few instances, however, Imitrex does not appear [illegible] contributory factor in these deaths.

1. The Purpose of Your Medicine:

Imitrex Tablets are intended to relieve your migraine, but not to prevent or reduce the number of attacks you experience. Use Imitrex Tablets only to treat an actual migraine attack.

2. Important Questions to Consider Before Taking Imitrex Tablets:

If the answer to any of the following questions is YES or if you do not know the answer, then please discuss with your doctor before you use Imitrex Tablets.

- Are you pregnant? Do you think you might be pregnant? Are you trying to become pregnant? Are you using inadequate contraception? Are you breastfeeding?
- Do you have any chest pain, heart disease, shortness of breath, or irregular heartbeats? Have you had a heart attack?
- Do you have risk factors for heart disease (such as high blood pressure, high cholesterol, obesity, diabetes, smoking, strong family history of heart disease, or you are postmenopausal or a male over 40)?
- Do you have high blood pressure?
- Have you ever had to stop taking this or any other medicine because of an allergy or other problems?
- Are you taking any other migraine medications, including migraine medications containing ergotamine or dihydroergotamine, or any medications containing monoamine oxidase inhibitor?
- Have you had, or do you have, any disease of the liver or kidneys?
- Have you had, or do you have, epilepsy or seizures?
- Is this headache different from your usual migraine attack?

Remember, if you answered YES to any of the above questions, then discuss it with your doctor.

ex Tablets During Pregnancy:

Tablets if you are pregnant, think you might be come pregnant, or are not using adequate con- e discussed this with your doctor.

ex Tablets:

dose is a single tablet taken whole with fluids. Ta the symptoms of your migraine appear, but it during an attack. A second tablet may be taken aine come back, but not sooner than 2 hours For a given attack, if you have no response to the econd tablet without first consulting with your than a total of 300 mg of Imitrex Tablets in any

tch for:

ıce pain or tightness in the chest or throat ıblets. If this happens to you, then discuss it e using any more Imitrex Tablets. If the chest ot go away, call your doctor immediately. ıeeziness; heart throbbing; swelling of eyelids, ash, skin lumps, or hives happens rarely. If it ll your doctor immediately. Do not take any nless your doctor tells you to do so. feelings of tingling, heat, flushing (redness of), heaviness or pressure after treatment with people may feel drowsy, dizzy, tired, or sick. e symptoms at your next visit. r other way or have any symptoms that you should contact your doctor immediately.

verdose is Taken:

medication than you have been told, contact emergency department, or nearest poison con-

ine:

ı safe place where children cannot reach it. It

way from heat and light. Do not store at tem- .

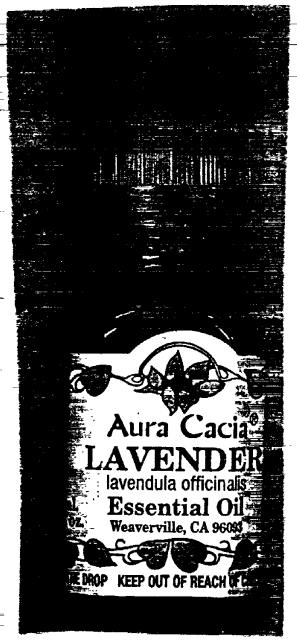
xpired (the expiration date is printed on the ay as instructed.

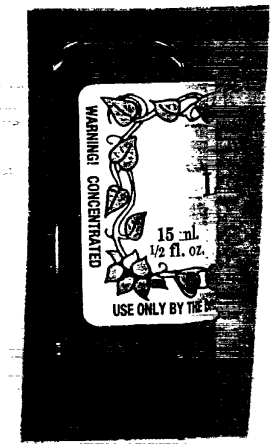
stop your treatment, do not keep any left- octor tells you to. Throw away your medicine

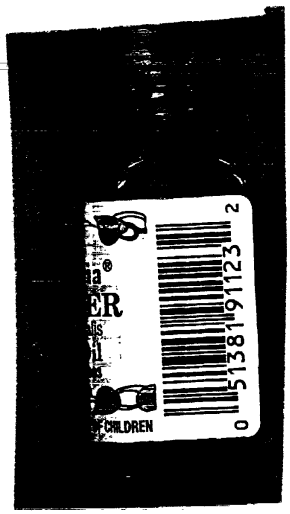
(1) Insert from Imitrex medication

CERENEX PHARMACEUTICALS
Division of Glaxo Inc.
Five Moore Drive, Research Triangle Park, NC 27709

RL-197 4054164 June 1995

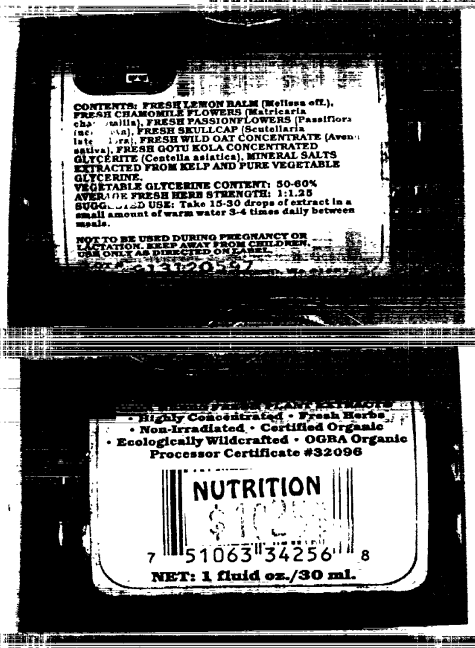






(1)

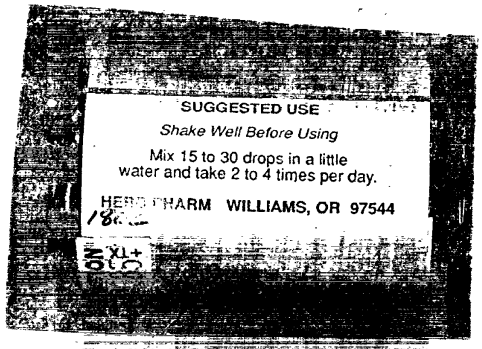
"Lavender" Essential Oil
1/2 fl. oz in glass bottle

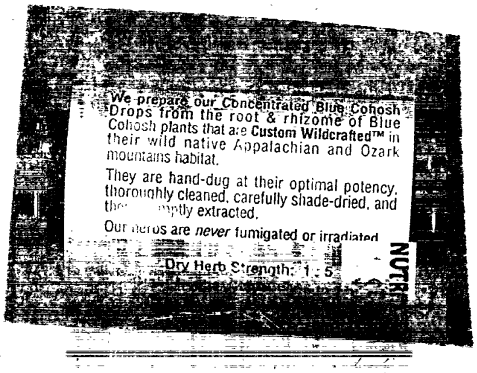


(2)

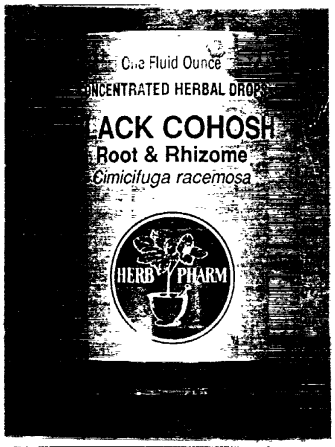
"Melissa Supreme"
Alcohol Free
Plant Extract

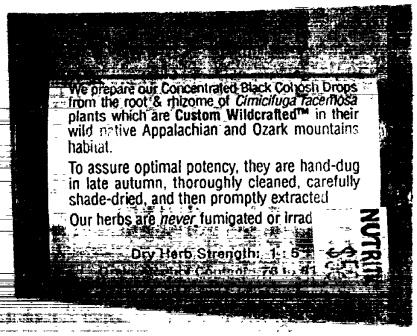
1 fl. oz glass
bottle w/dropper

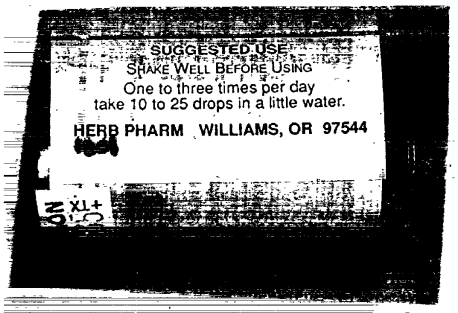




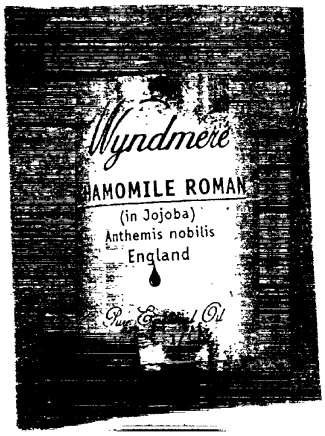
(3) "Blue Cohosh" Root & Rhizome Concentrated Herbal Drops
1 fl. oz. glass bottle w/dropper

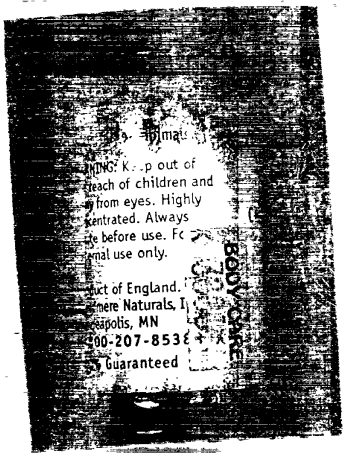




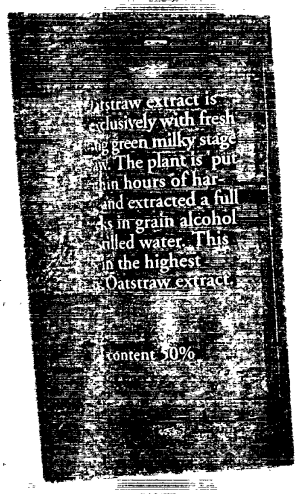


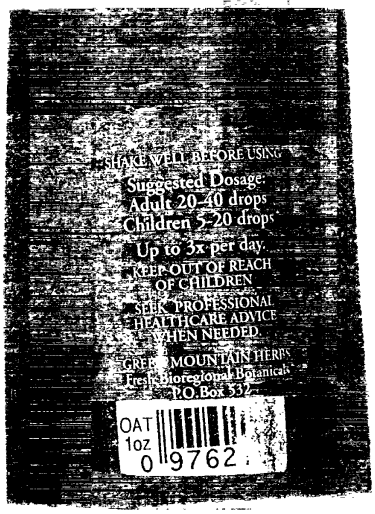
(4) "Black Cohosh" Root & Rhizome Concentrated Herbal Drops
1 fl. oz. glass bottle w/dropper



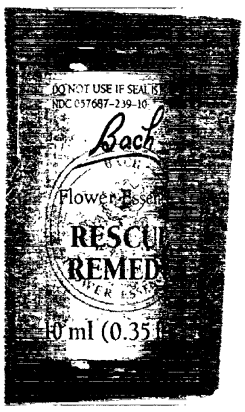


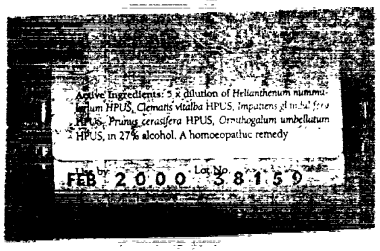
(5) "Chamomile Roman" Pure Essential Oil
1/3 oz blue glass bottle. For external use only.

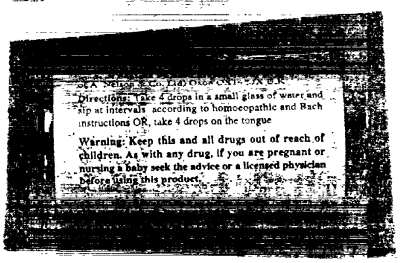




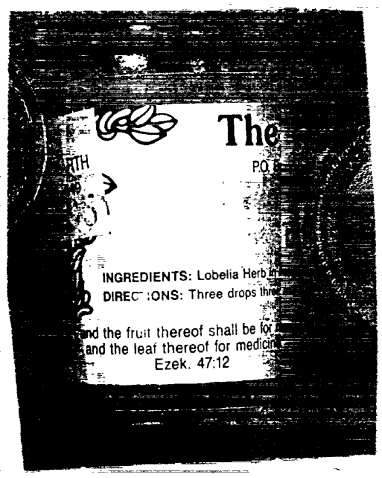
(6) "Oatstraw" Extract
1 fl. oz glass bottle w/dropper

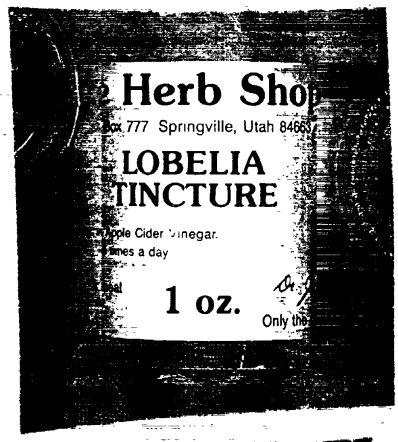






(7) Bach "Rescue Remedy"
0.35 fl. oz glass
bottle w/dropper

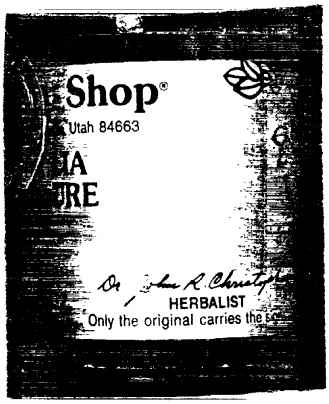


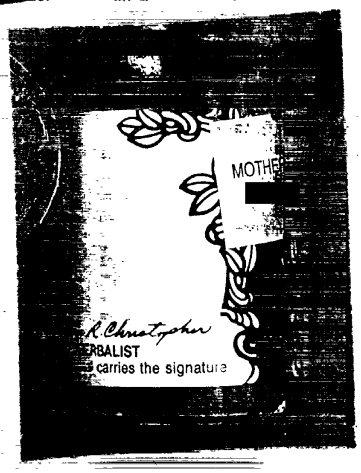


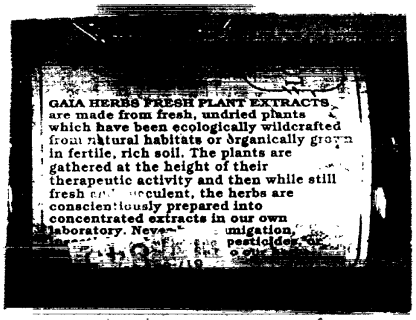
(8)

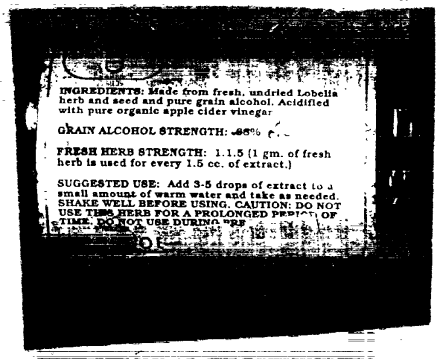
"Lobelia" Tincture

1 fl. oz. glass bottle w/dropper



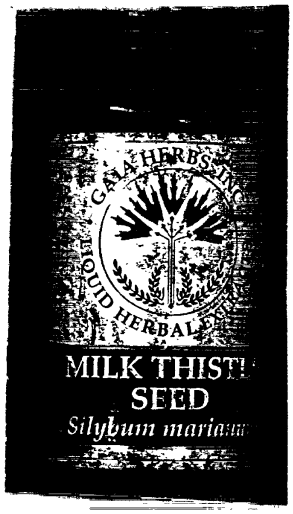


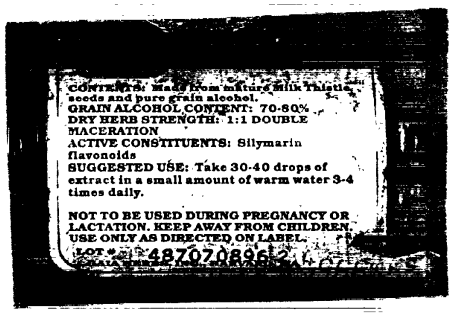


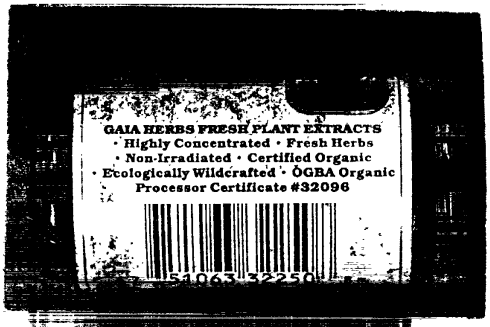


(9) "Fresh Lobelia Herb & Seed" Plant Extract

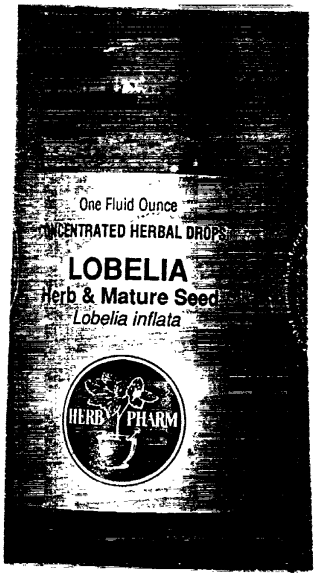
1 fl. oz. glass bottle w/stopper

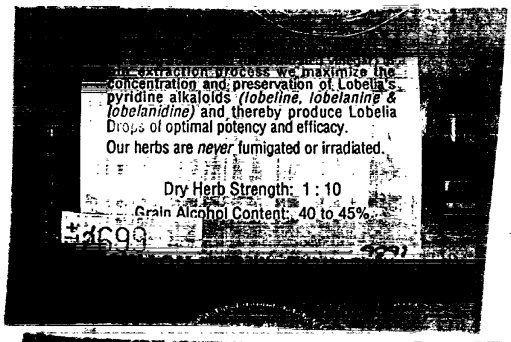


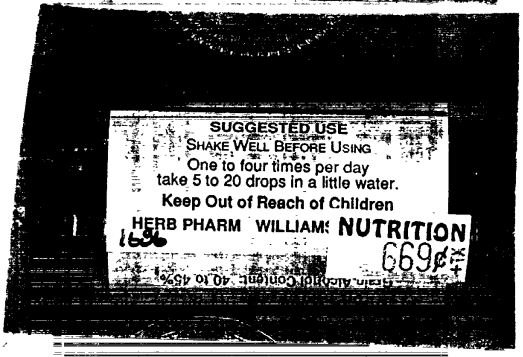


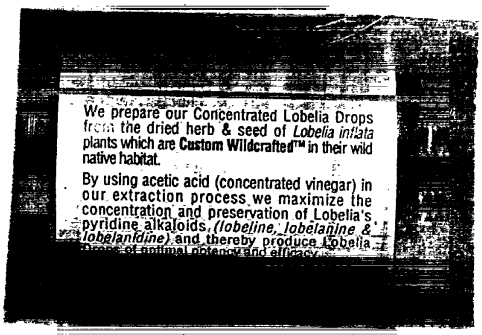


(10) "Milk Thistle Seed" Herbal Extract
1 fl oz glass bottle w/dropper

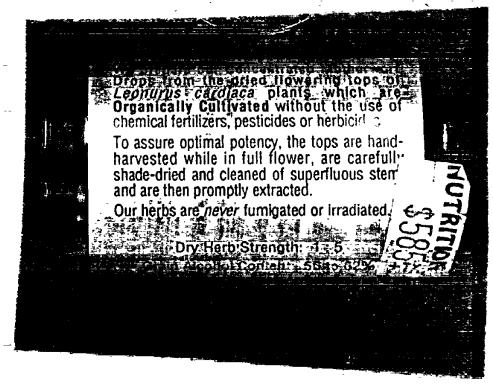


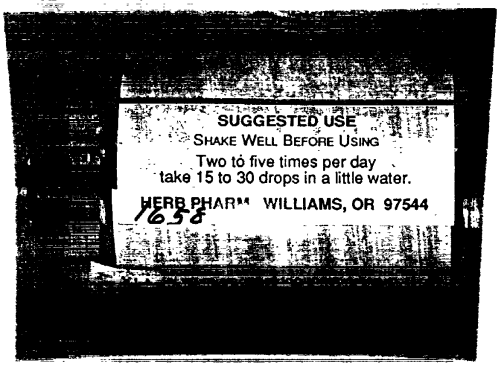




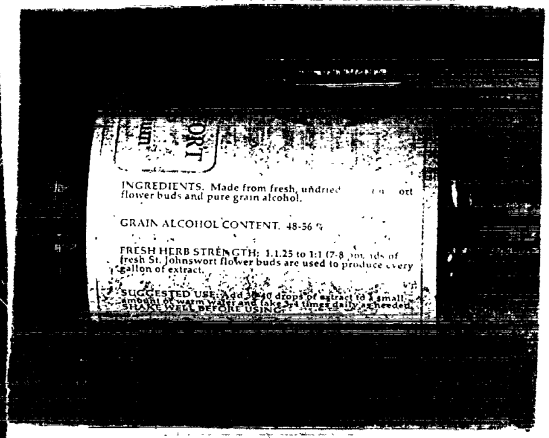


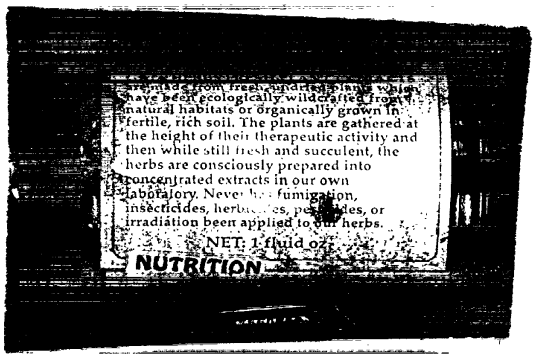
(11) "Lobelia" Concentrated Herbal Drops
1 fl. oz glass bottle w/dropper
(2 bottles)



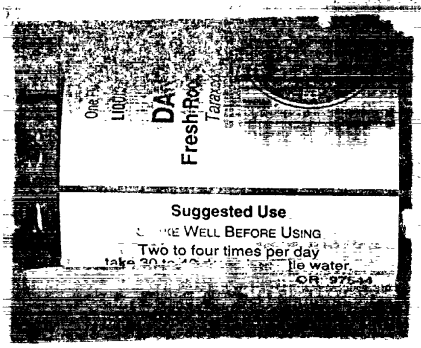


(12) "Motherwort" Concentrated Herbal Drops
1 fl.oz glass bottle w/dropper



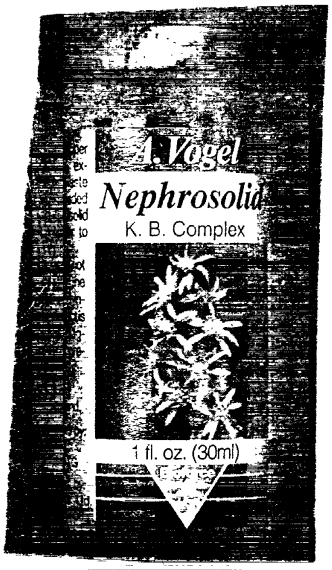


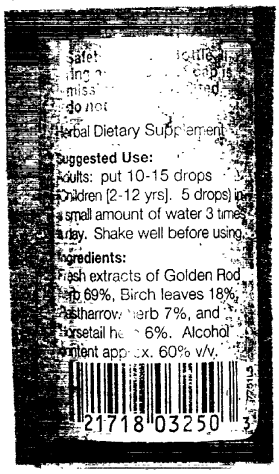
(13) "Fresh St. Johnswort flower Buds" Plant Extract
1 fl. oz glass bottle w/dropper

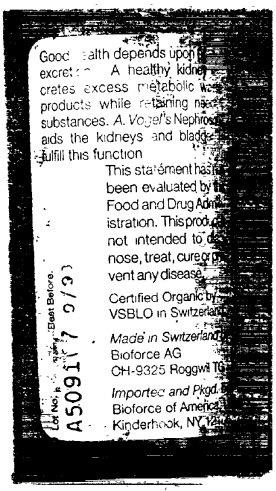


(14) "Dandelion" fresh Root, Leaf & flower
liquid Herbal Extract
1 fl oz glass bottle w/dropper

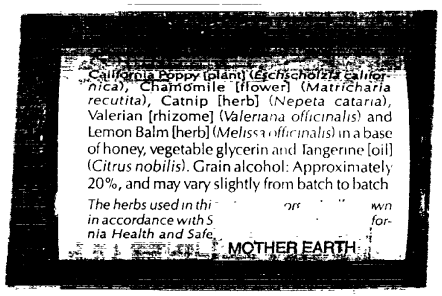
000013

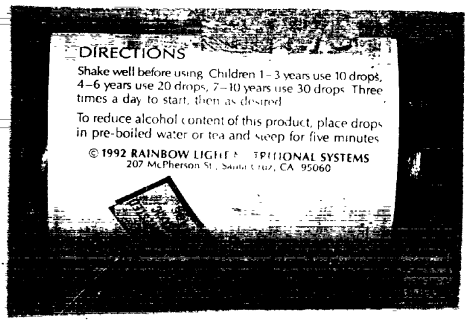






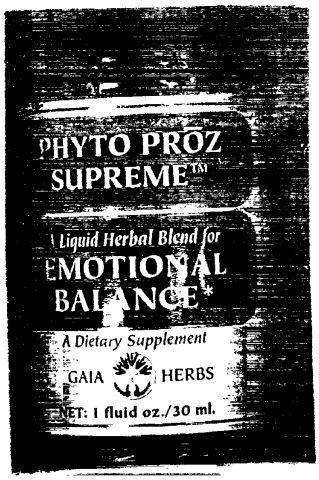
(15) "Nephrosolid" Herbal Dietary Supplement
1 fl. oz. glass bottle

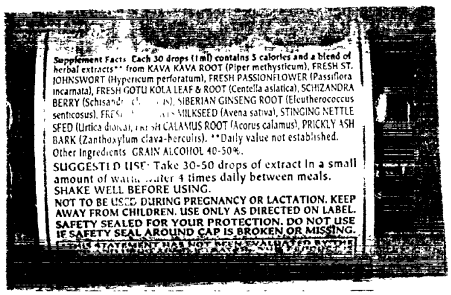


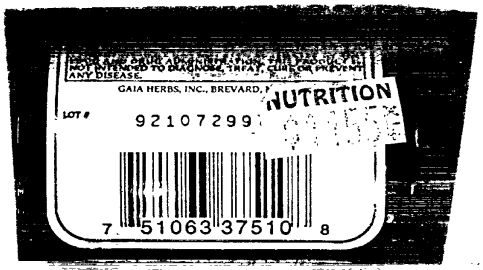


(16) "Children's Relax" herbal extract
1 fl. oz glass bottle w/dropper

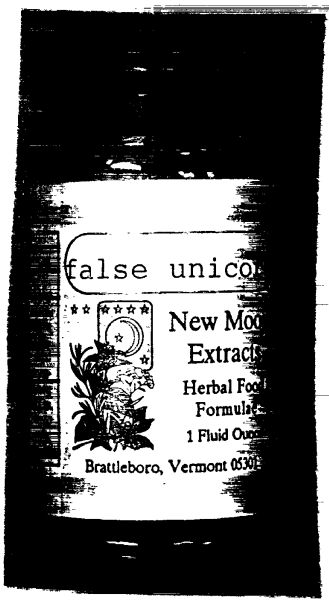
000014

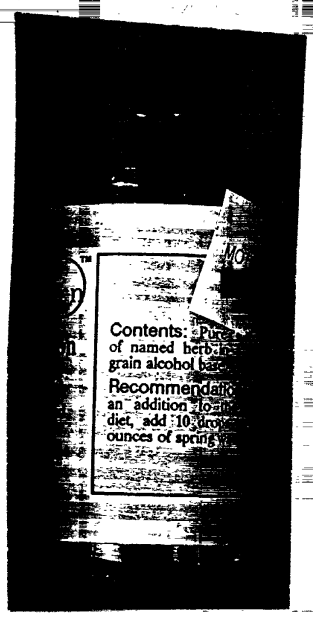


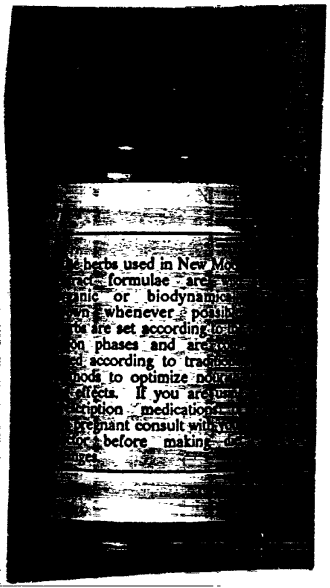




(17) "Phyto Proz Supreme" - A Liquid Herbal Blend for Emotional Balance
1 fl. oz. glass bottle w/dropper

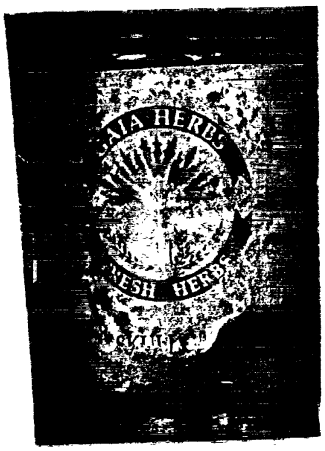


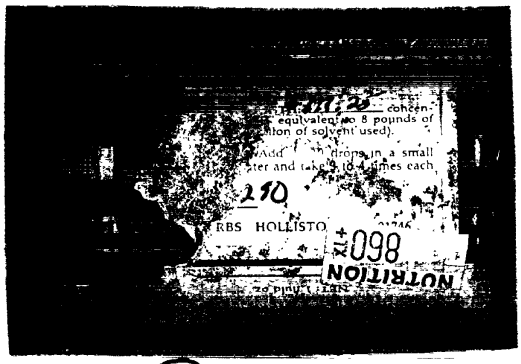




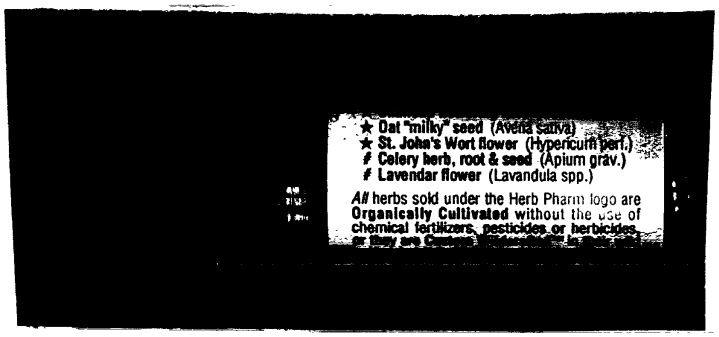
(18) "False Unicorn" Herbal Food Formulae
1 fl. oz. bottle w/dropper (3 bottles)

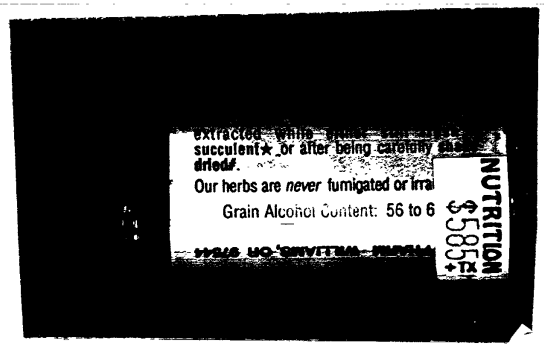
000015





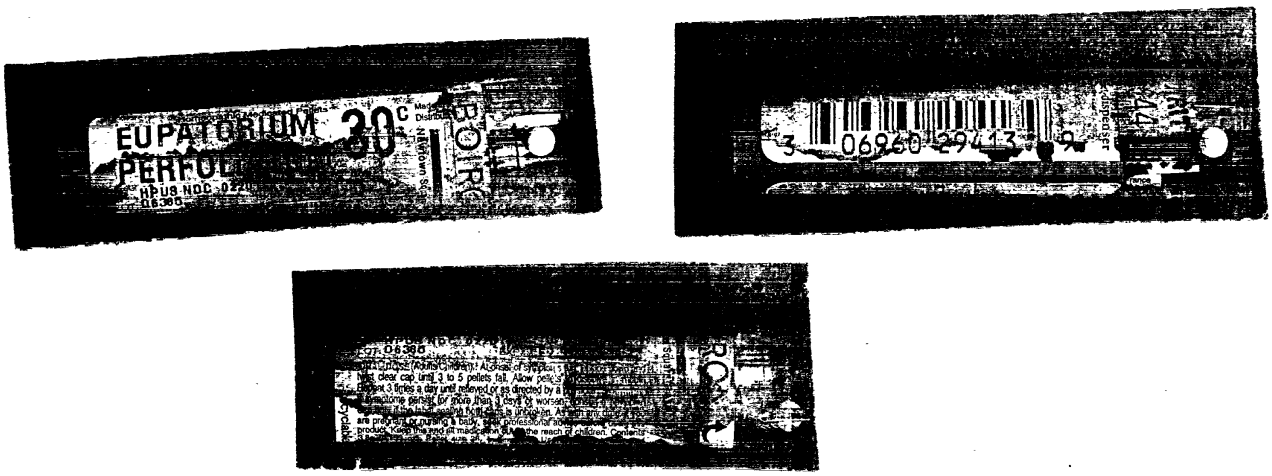
(19) "Skullcap"
1 Fl. oz. glass bottle w/dropper



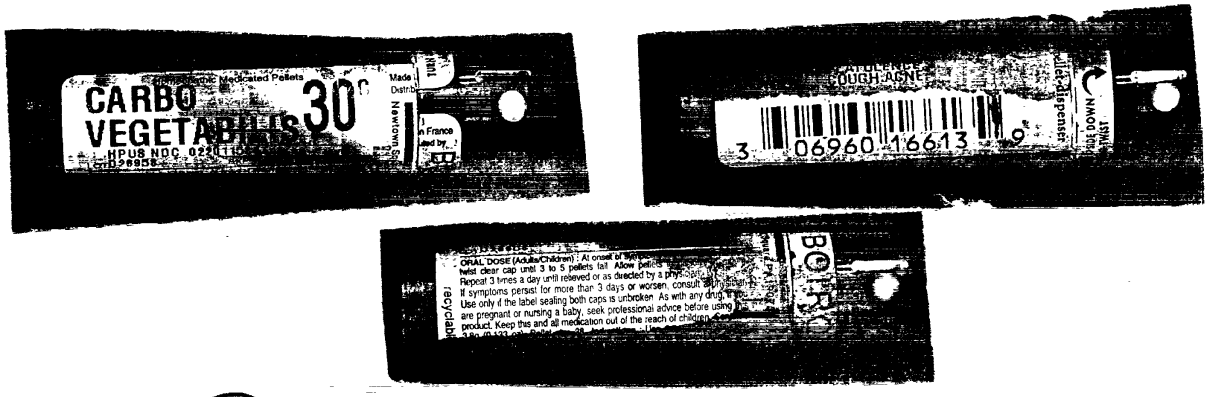


(20) "Skullcap" Compound Concentrated Herbal Drops
1 fl. oz. glass bottle w/dropper

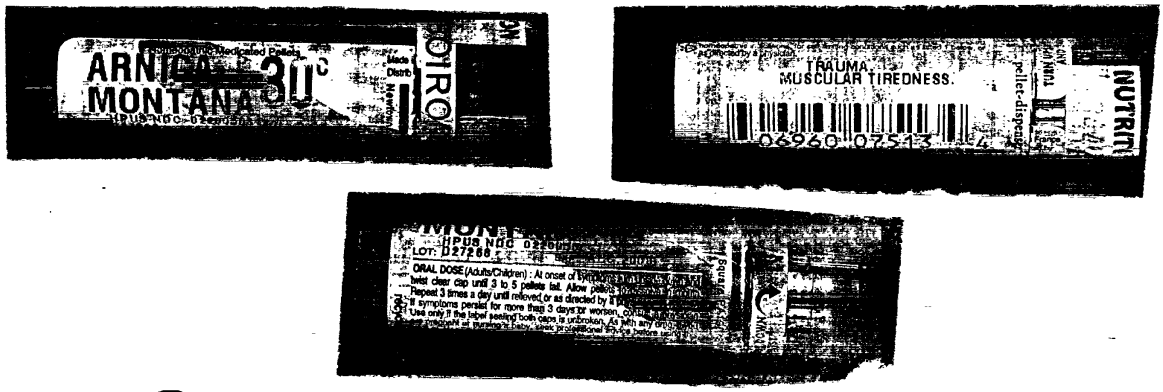
BIORON
Homeopathic Medicated Pellets
0.133 oz plastic pellet dispenser



(21) "Eupatorium Perfoliatum"

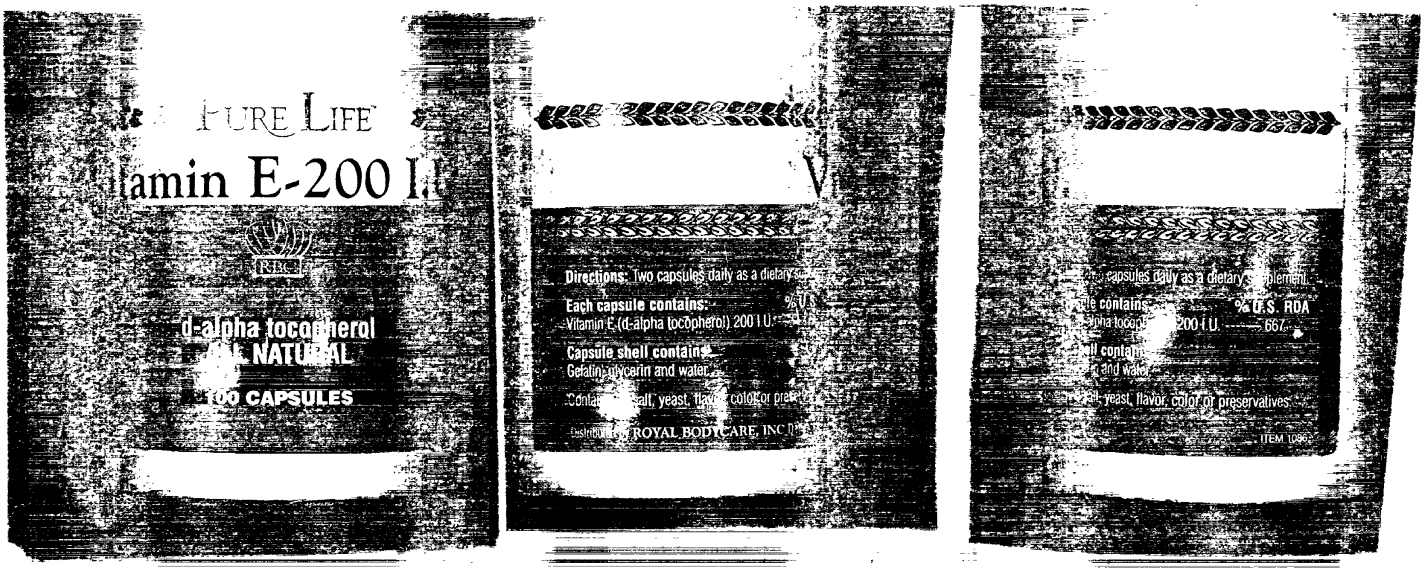


(22) "carbo Vegetabilis"

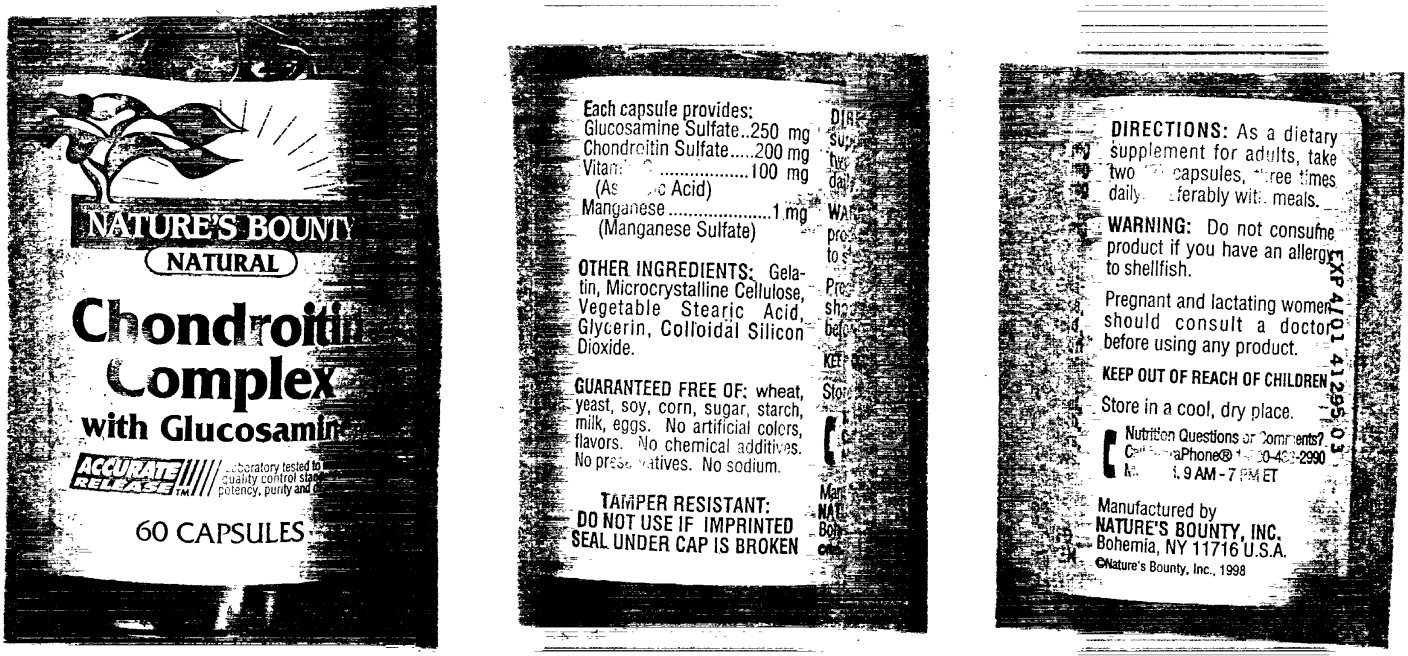


(23) "Arnica Montana"

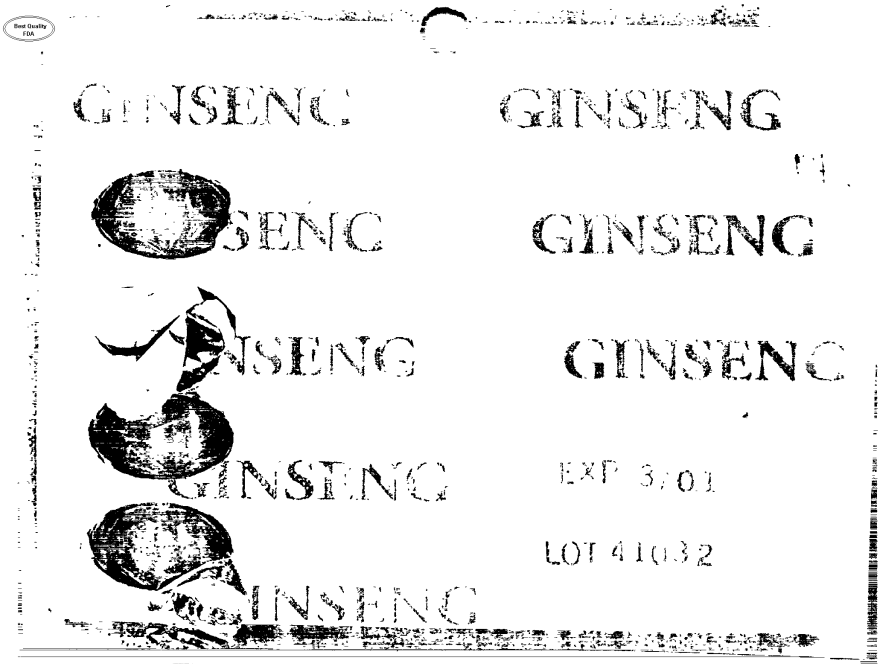
000017



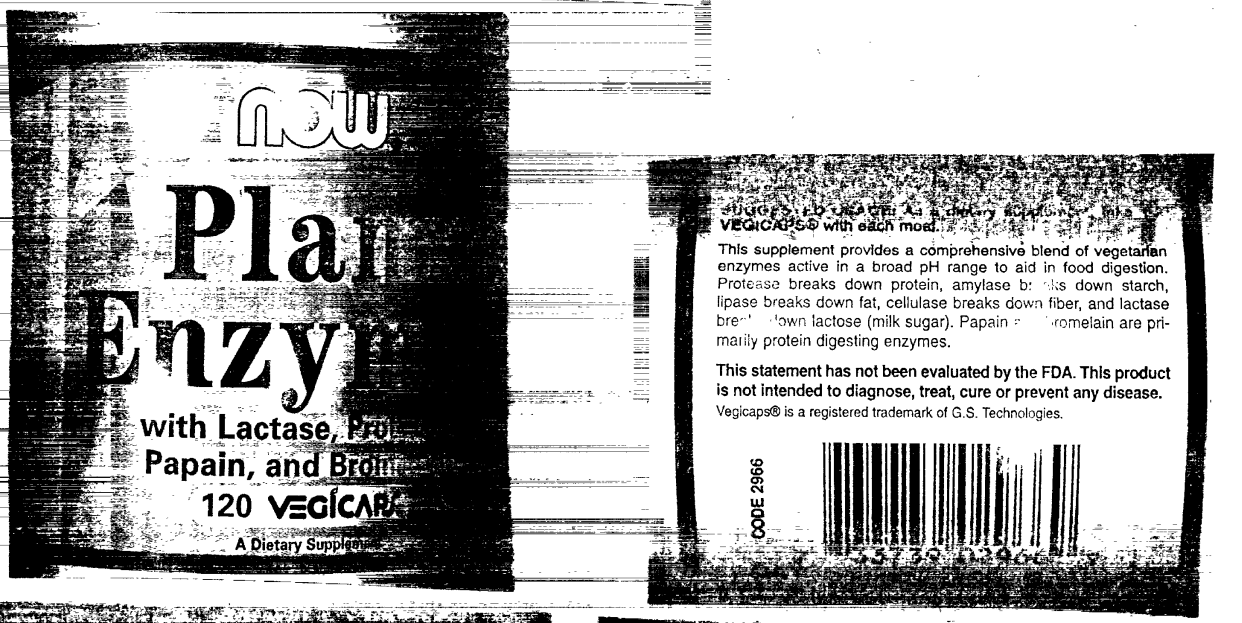
(24) "Vitamin E-200 I.U."
~~ZESTAB~~ 100 ~~Caps~~ - plastic bottle



(25) "Chondroitin Complex w/Glucosamine"
60 caps - plastic bottle
(2 bottles)

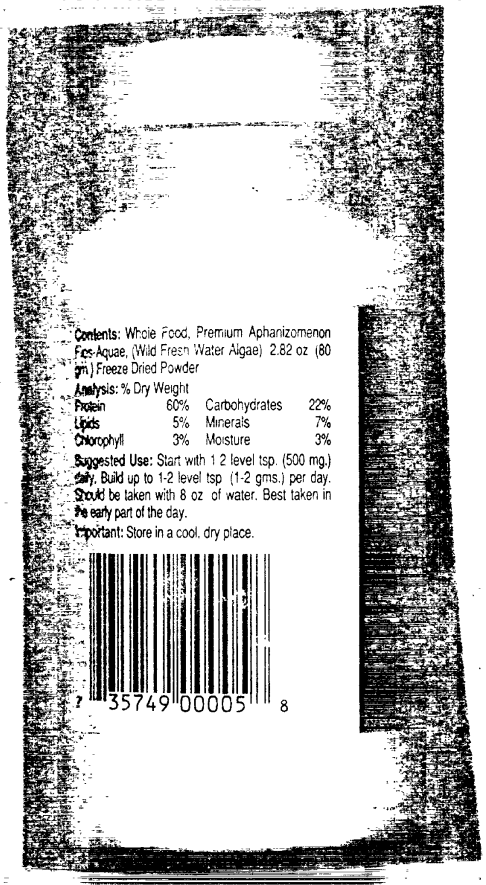


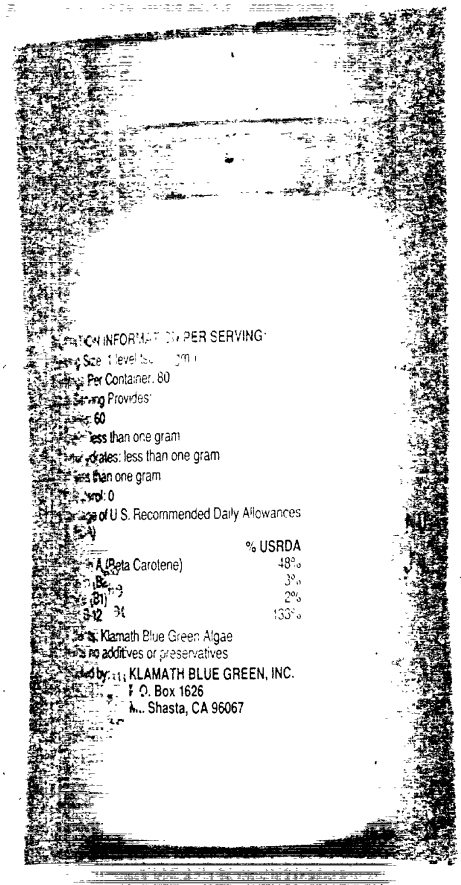
(26) "Ginseng" tablets 20 unit blister pack



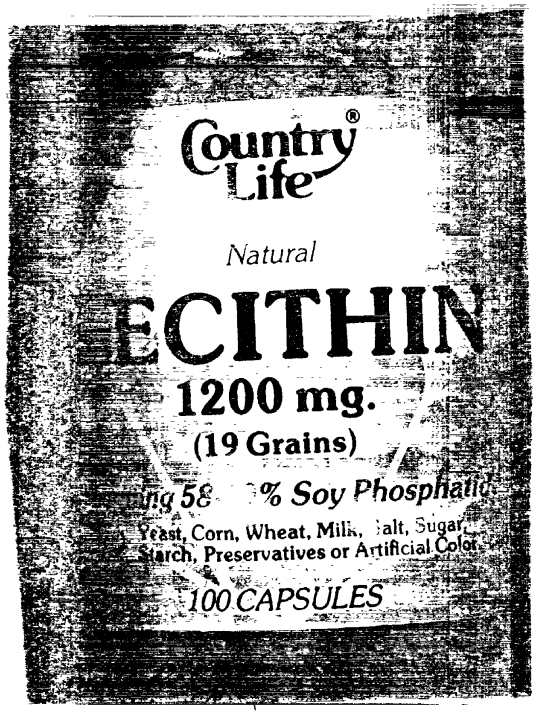
(27) "Plant Enzymes" with Lactase, Protease, Papain and Bromelain
120 Vegicaps - Plastic bottle

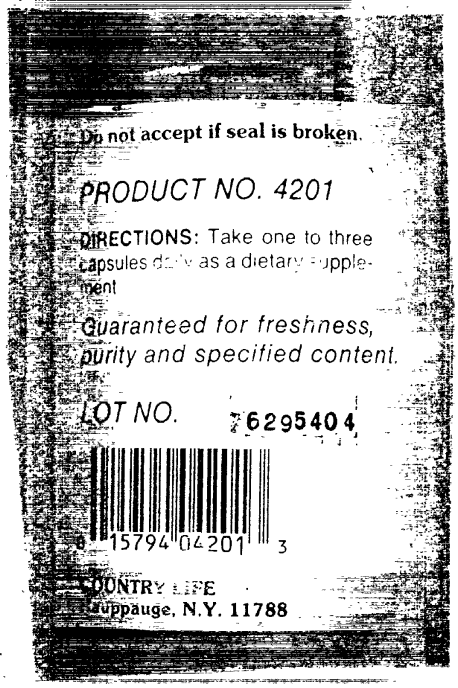
000019

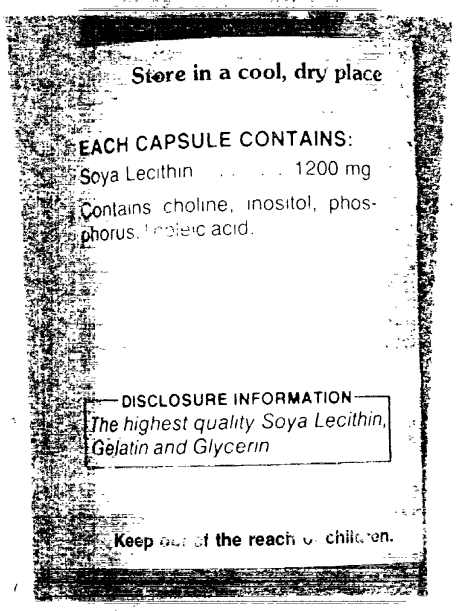




(28) "Blue Green Algae" Whole Food Freeze Dried Powder 2.82 oz (80g)

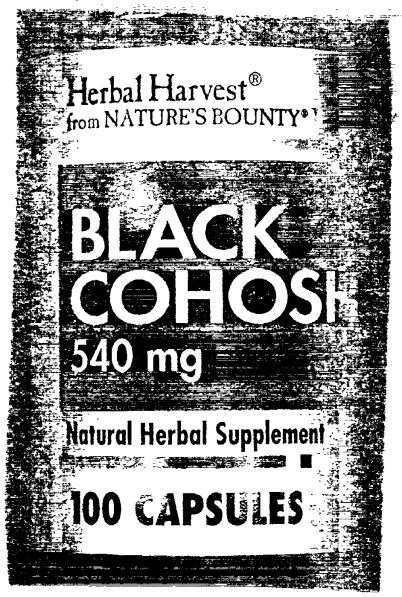


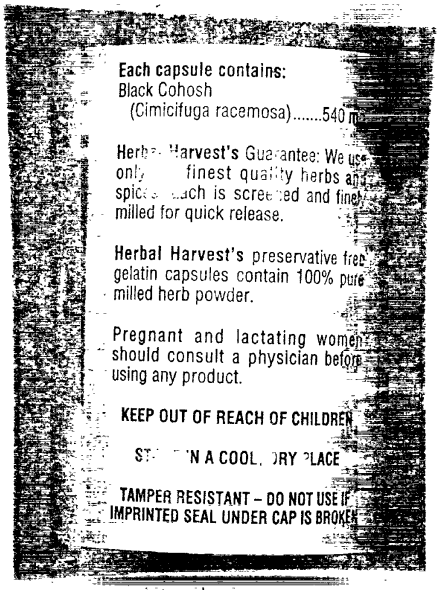




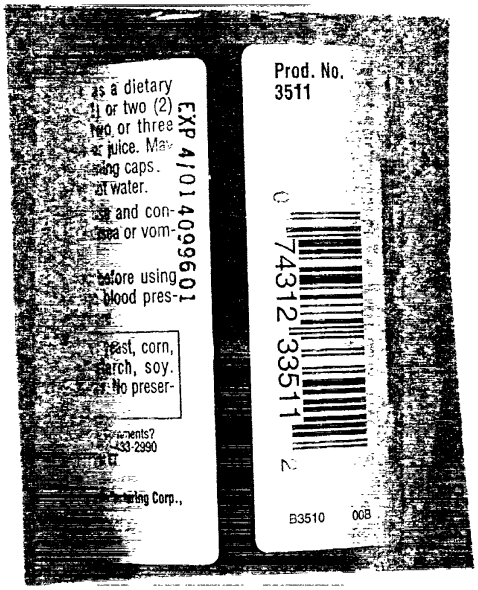
(29) "Lecithin" 1200 mg 100 caps - glass bottle

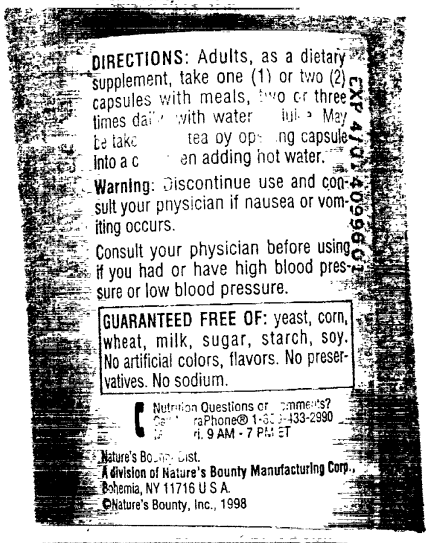
000020

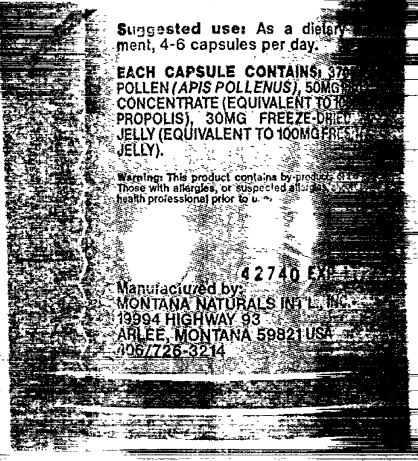


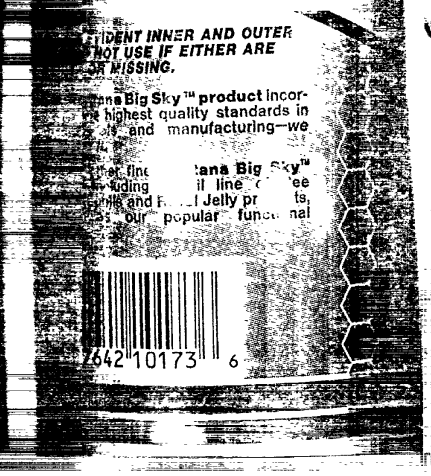


(30)
"Black Cohosh"
540 mg
Natural Herbal
Supplement
100caps - plastic
bottle



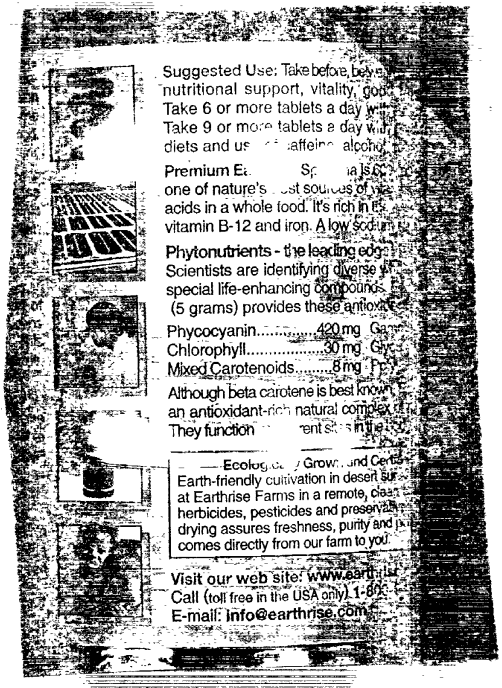


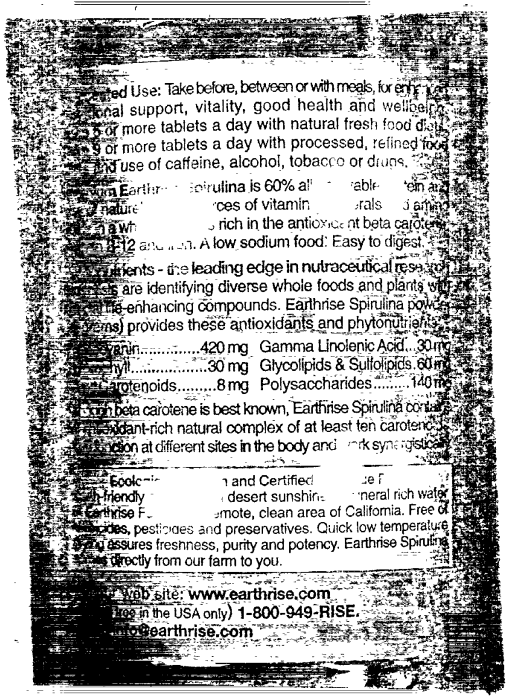


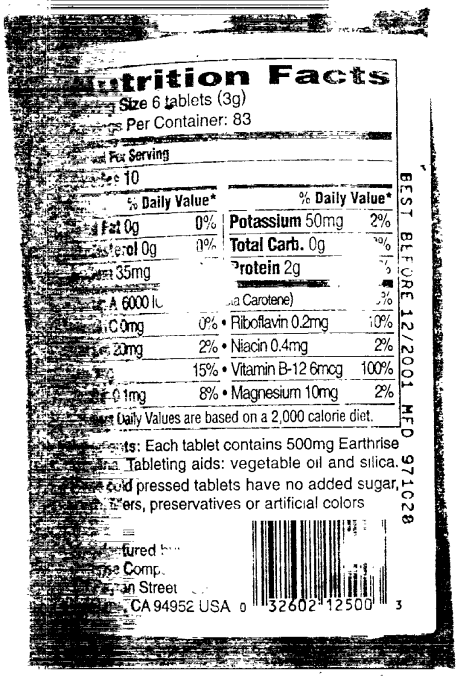


(31)
"Bee Pollen
Royal Jelly
& Propolis"
Capsules
450mg
90caps
plastic
bottle

000021

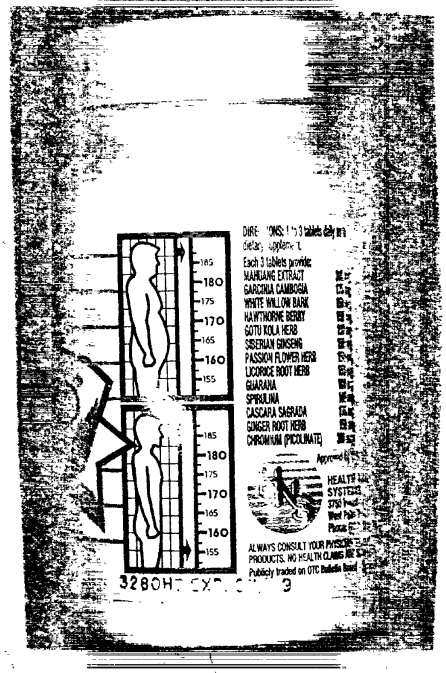






(32) "Spirulina" Blue Green Algae
500 Tablets
glass bottle

000022



(33)

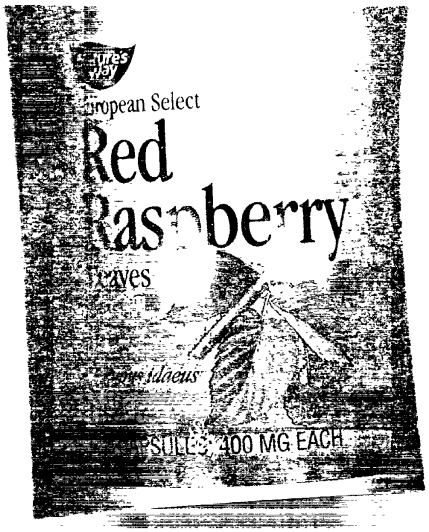
"THINTAB 100"

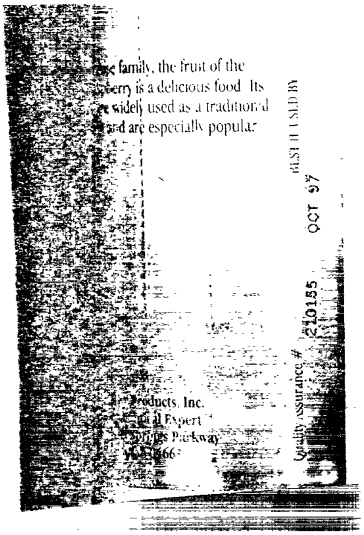
Stimulates Weight Loss

Pure Herb Supplement

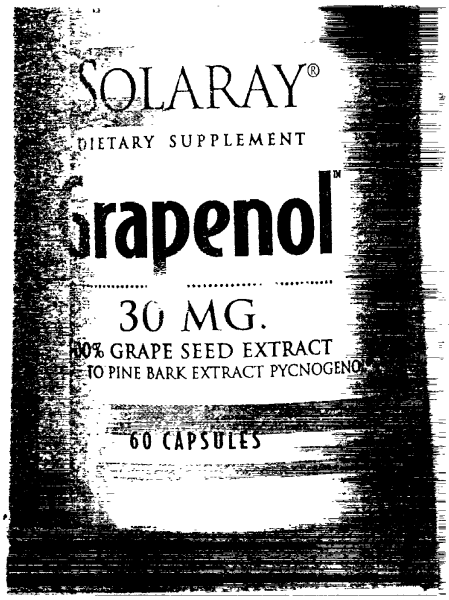
30 Tabs

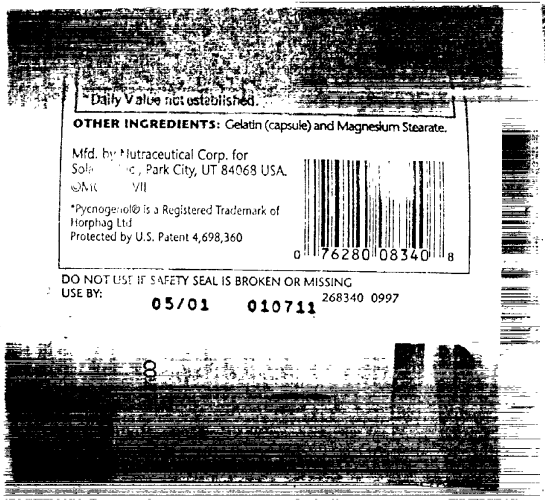
plastic bottle

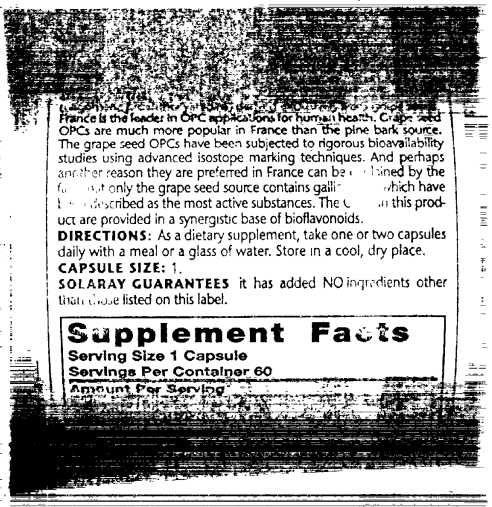




(34) "Red Raspberry" Leaves
100 caps / 400 mg each
plastic bottle

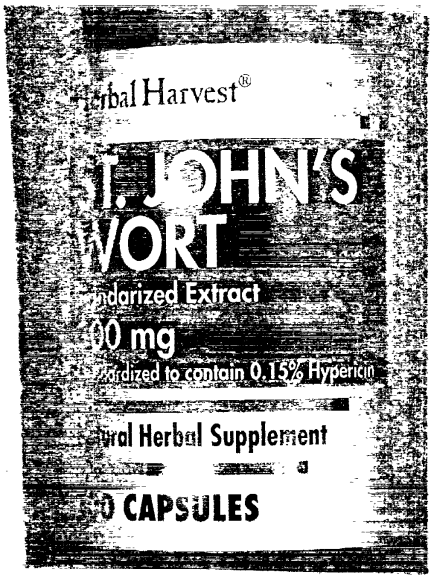


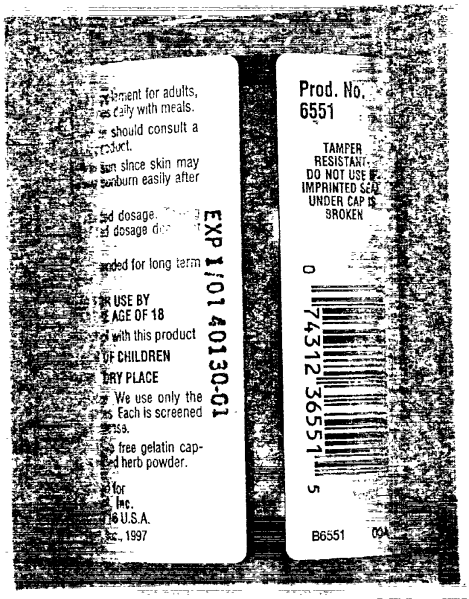


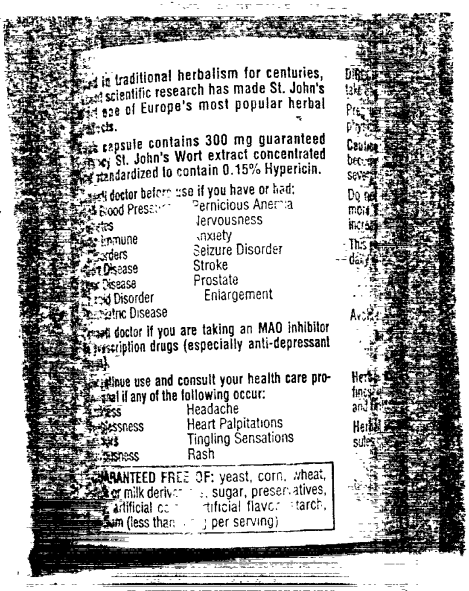


(35) "Grapenol" Dietary Supplement
30 mg 100% Grape Seed Extract
60 caps - plastic bottle

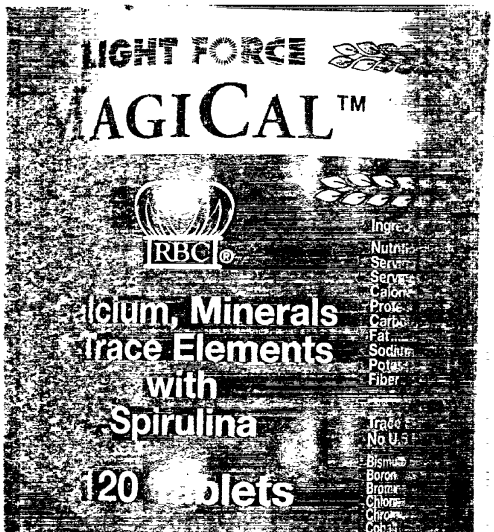
000024

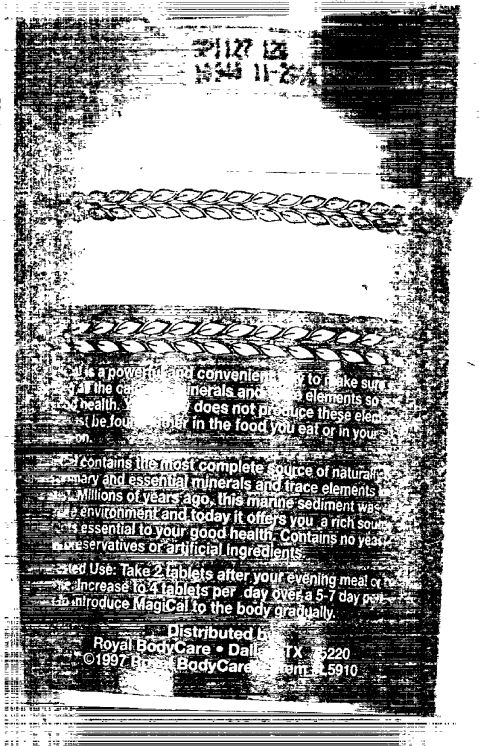


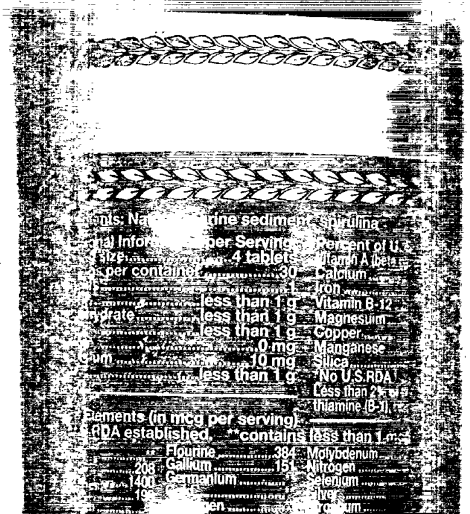




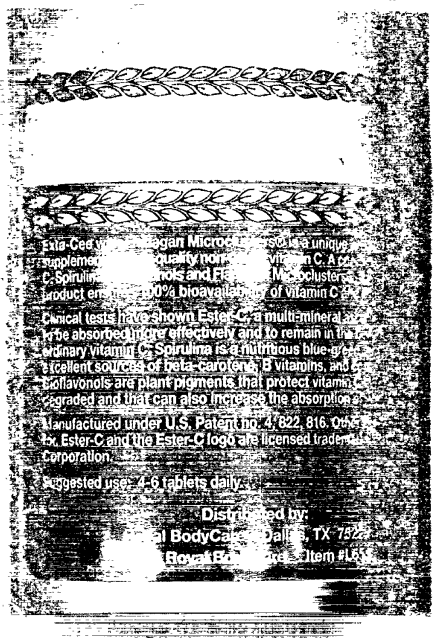
(36) "St. John's Wort" Standardized Extract - 100 caps
300 mg - standardized to contain 0.15% Hypericin
(plastic bottle)

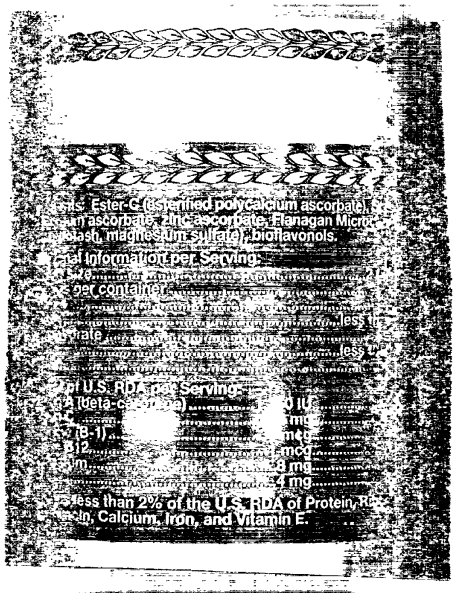




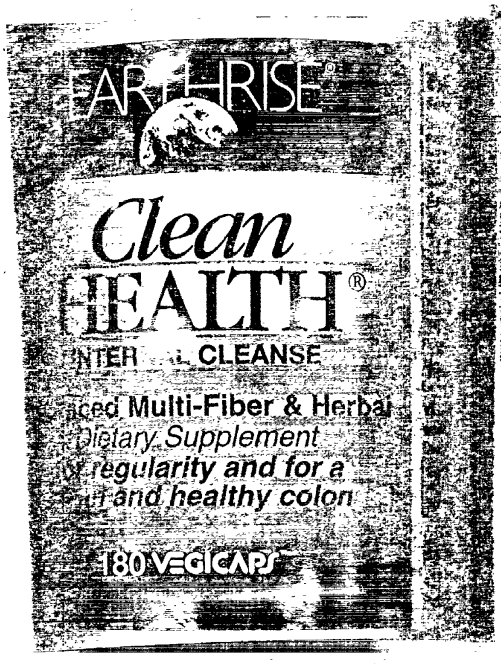


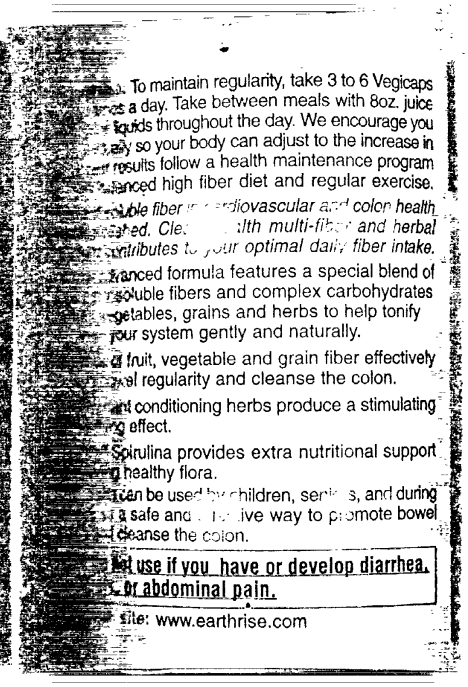
(37) "MagiCal" Calcium, Minerals & Trace Elements
with Spirulina
120 Tabs - plastic ~~bottle~~

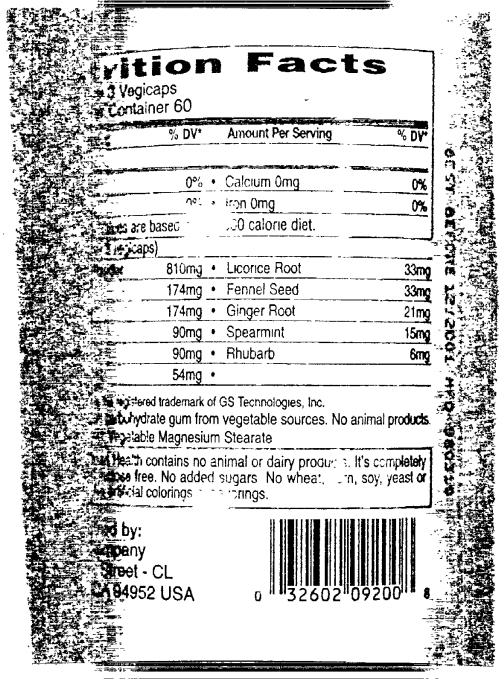




(38) *Spirulina and Ester-C® with Flanagan Microclusters
200 Tablets - plastic bottle
(2 bottles)

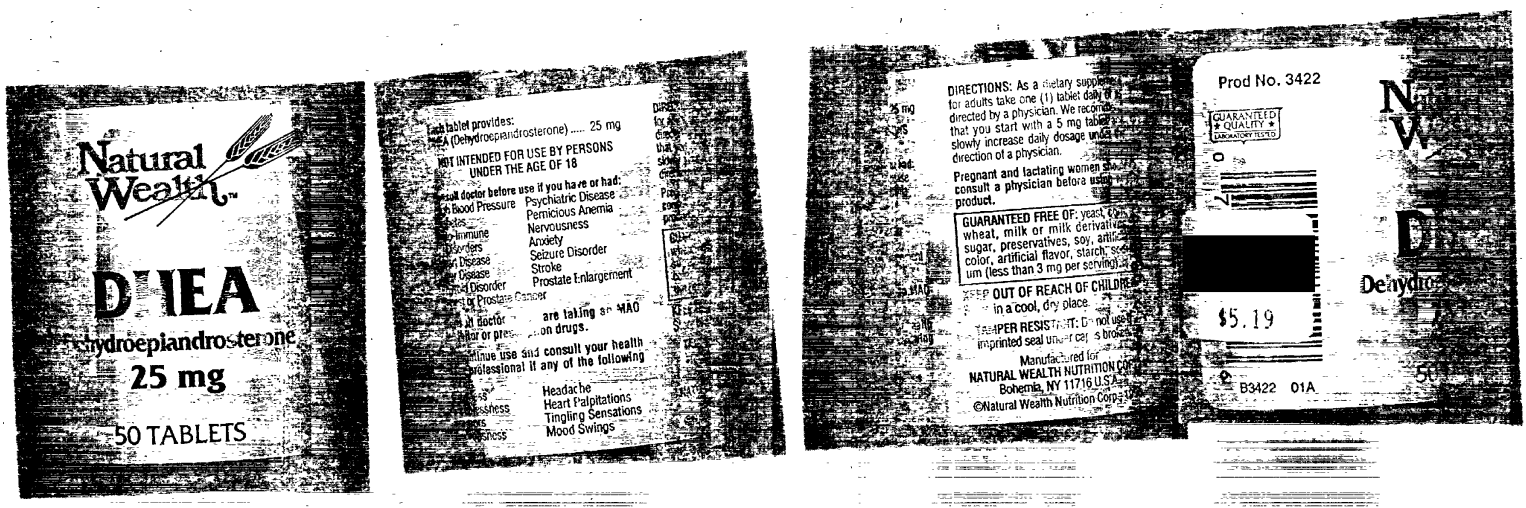




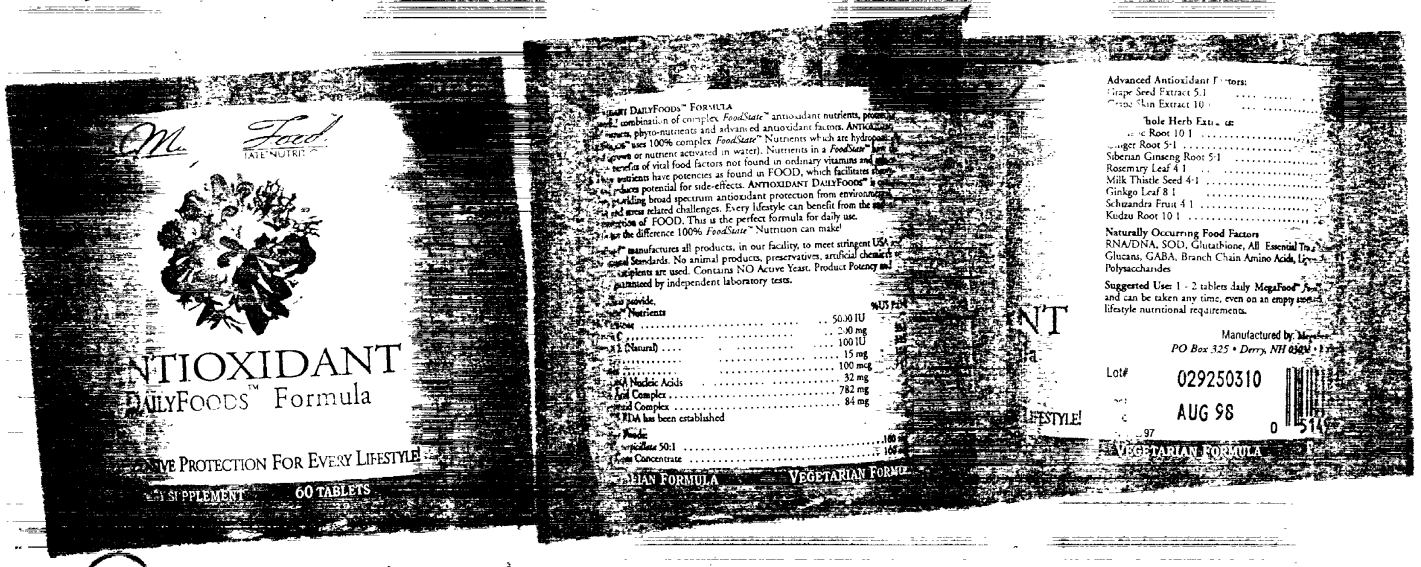


(39) *Internal Cleanse" Advanced Multi-Fiber & Herbal Dietary Supplement
180 vegicaps - plastic bottle

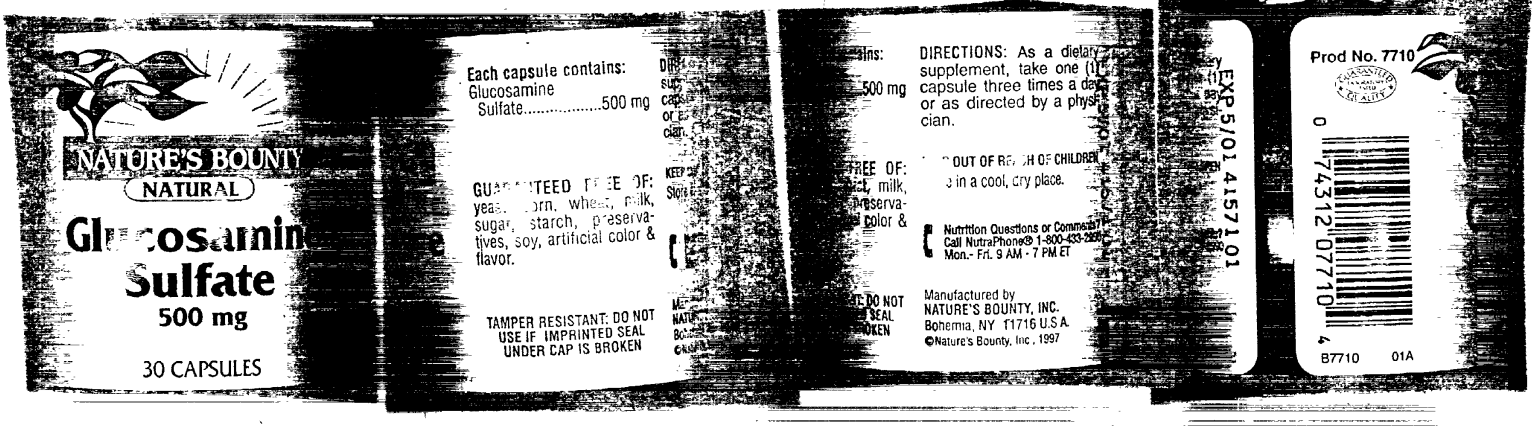
000026



(40) "DHEA" (Dehydroepiandrosterone) 25mg
50 tabs - plastic bottle

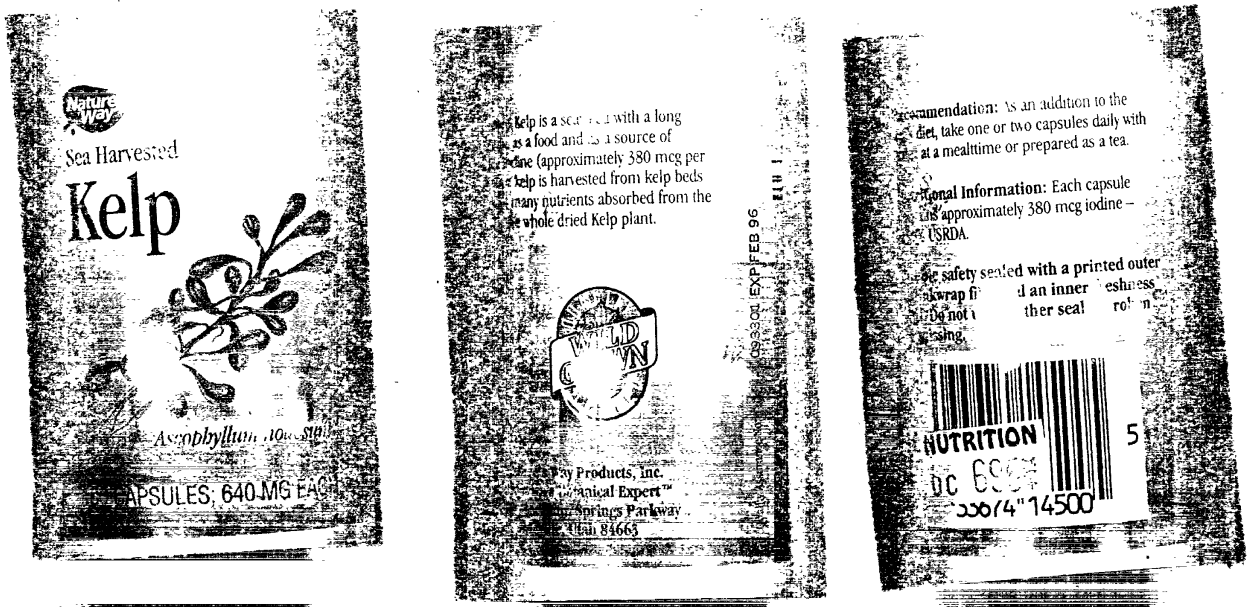


(41) "Antioxidant"
Dietary Supplement - 60 tabs - glass bottle

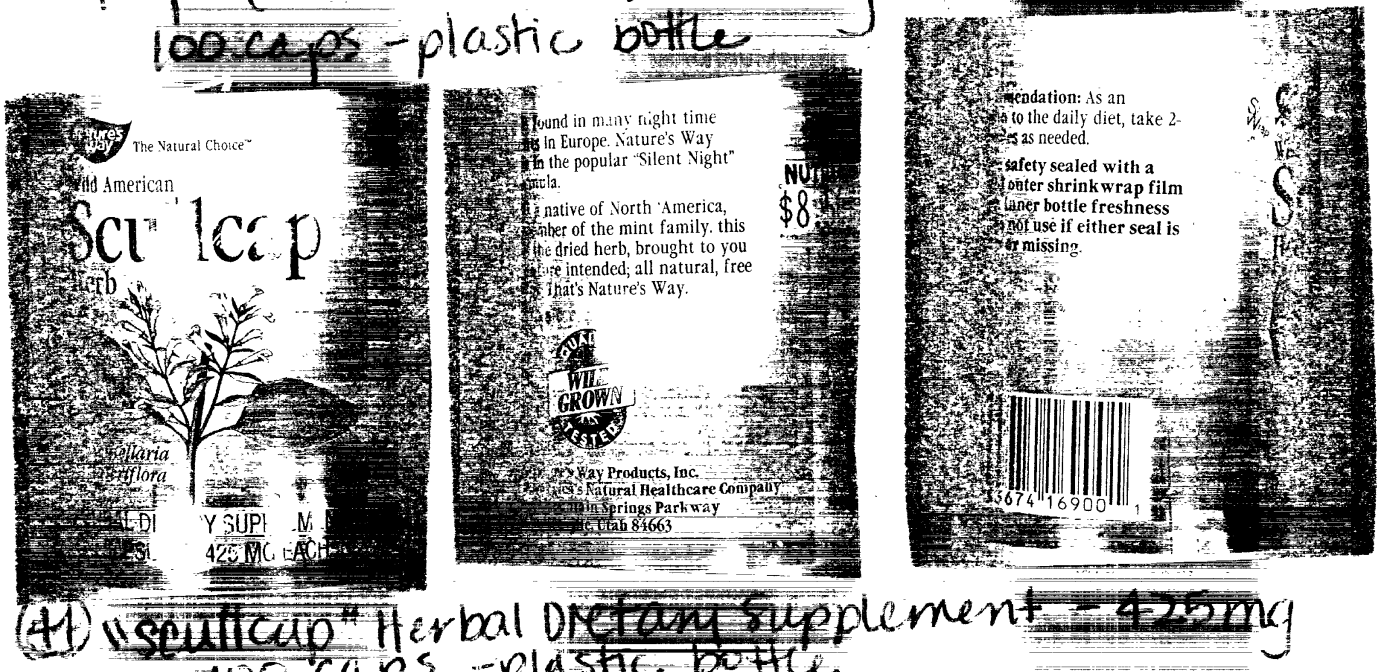


(42) "Glucosamine Sulfate" 500mg
30 caps - plastic bottle

000027

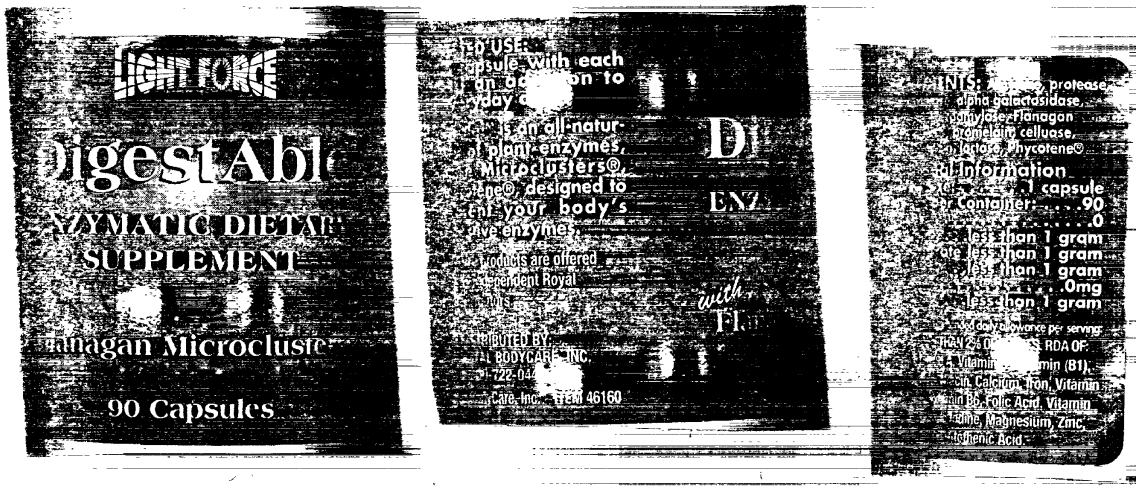


(43) "Kelp" (sea Harvested) 640 mg
100 caps - plastic bottle



(41) "Scullcap" Herbal Dietary Supplement - 425mg
100 caps - plastic bottle

000028

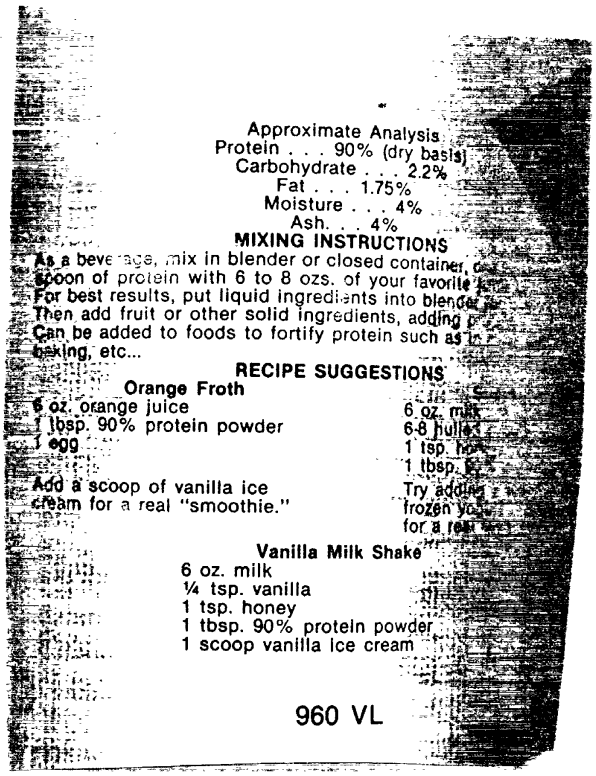


(45) "Digestable" Enzymatic Dietary Supplement with Flanagan Microclusters 90 caps plastic bottle

(46) "Pro-90 Blend" - Powder

000029

(46) Labeling from "Pro-90 Blend" powder



Approximate Analysis
Protein . . . 90% (dry basis)
Carbohydrate . . . 2.2%
Fat . . . 1.75%
Moisture . . . 4%
Ash. . . 4%

MIXING INSTRUCTIONS

As a beverage, mix in blender or closed container, one heaping tablespoon of protein with 6 to 8 ozs. of your favorite juice or beverage. For best results, put liquid ingredients into blender jar; turn on mixer. Then add fruit or other solid ingredients, adding protein powder last. Can be added to foods to fortify protein such as in meat loaf, cereal, baking, etc...

RECIPE SUGGESTIONS

Orange Froth

6 oz. orange juice
1 tbsp. 90% protein powder
1 egg

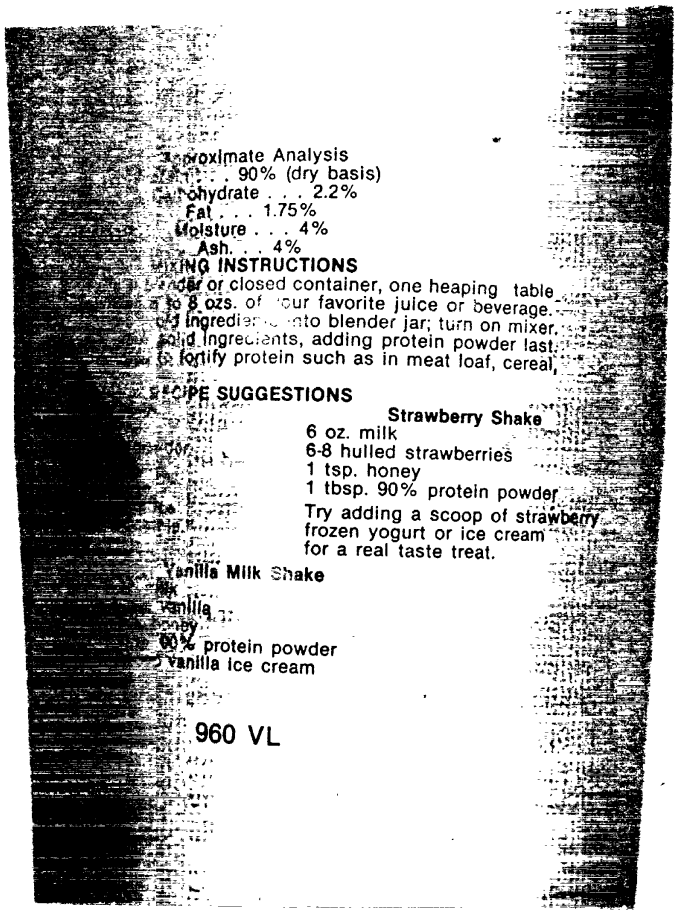
Add a scoop of vanilla ice cream for a real "smoothie."

6 oz. milk
6-8 hulled
1 tsp. ho
1 tbsp. 9
Try adding
frozen yo
for a rea

Vanilla Milk Shake

6 oz. milk
¼ tsp. vanilla
1 tsp. honey
1 tbsp. 90% protein powder
1 scoop vanilla ice cream

960 VL



Approximate Analysis
. . . 90% (dry basis)
ohydrate . . . 2.2%
Fat . . . 1.75%
Moisture . . . 4%
Ash. . . 4%

MIXING INSTRUCTIONS

der or closed container, one heaping table
to 8 ozs. of our favorite juice or beverage.
d ingredie nto blender jar; turn on mixer.
olid ingredients, adding protein powder last.
o fortify protein such as in meat loaf, cereal,

PE SUGGESTIONS

Strawberry Shake

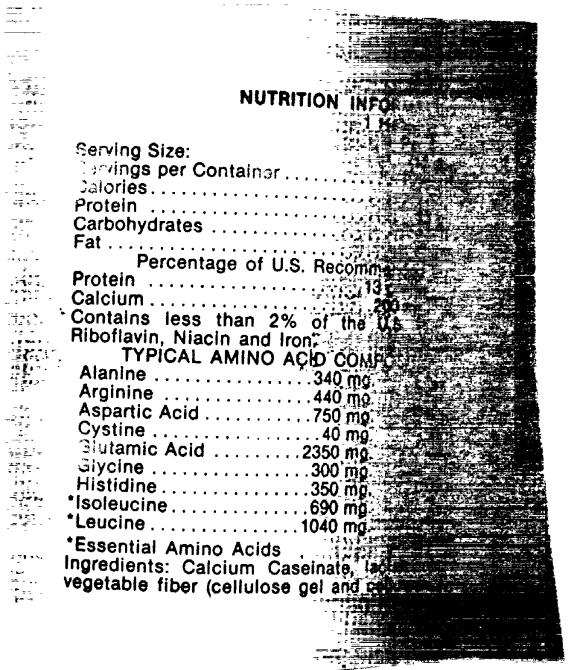
6 oz. milk
6-8 hulled strawberries
1 tsp. honey
1 tbsp. 90% protein powder

Try adding a scoop of strawberry frozen yogurt or ice cream for a real taste treat.

anilla Milk Shake

anilla
ney
90% protein powder
vanilla ice cream

960 VL



NUTRITION INFO

1 Ta

Serving Size:
ervings per Container
alories
Protein
Carbohydrates
Fat

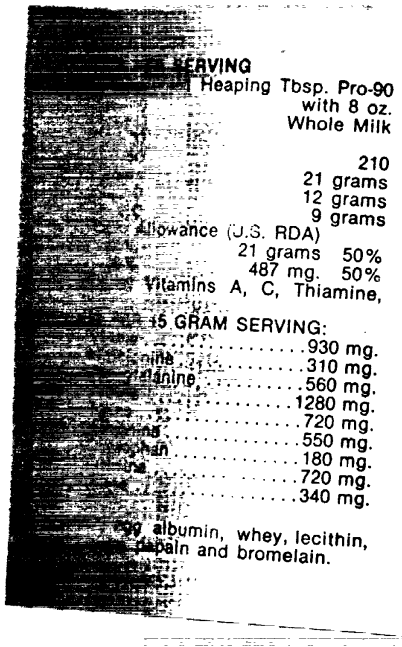
Percentage of U.S. Recomm
Protein 13
Calcium 20
Contains less than 2% of the U.S.
Riboflavin, Niacin and Iron.

TYPICAL AMINO ACID COMP

Alanine	340 mg.
Arginine	440 mg.
Aspartic Acid	750 mg.
Cystine	40 mg.
Glutamic Acid	2350 mg.
Glycine	300 mg.
Histidine	350 mg.
*Isoleucine	690 mg.
*Leucine	1040 mg.

*Essential Amino Acids

Ingredients: Calcium Caseinate, la
vegetable fiber (cellulose gel and p



ERVING

Heaping Tbsp. Pro-90
with 8 oz.
Whole Milk

210
21 grams
12 grams
9 grams

llowance (U.S. RDA)
21 grams 50%
487 mg. 50%
Vitamins A, C, Thiamine,

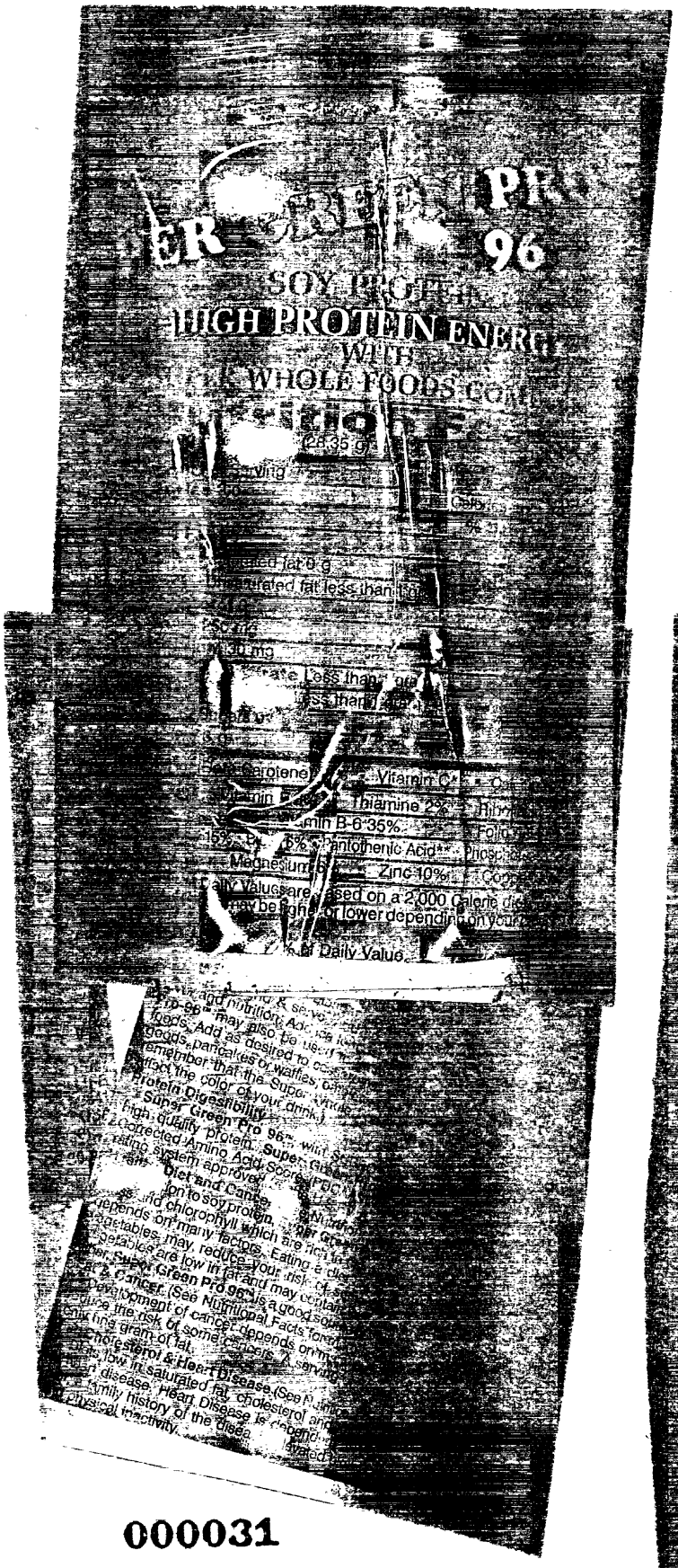
5 GRAM SERVING:

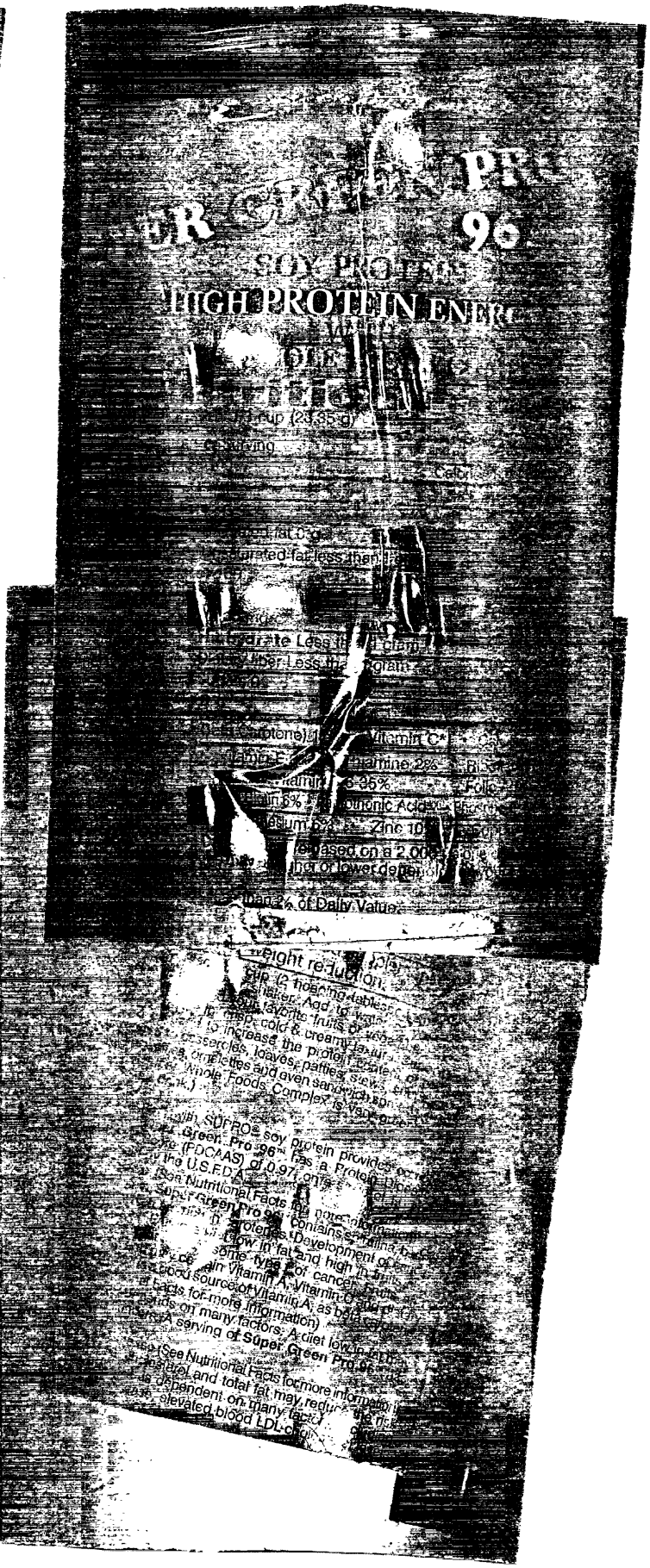
	930 mg.
nine	310 mg.
nine	560 mg.
	1280 mg.
	720 mg.
	550 mg.
an	180 mg.
	720 mg.
	340 mg.

99 albumin, whey, lecithin,
papain and bromelain.

000030

(47) Super Green Pro 96 - Soy Protein High Protein Energy with Super Whole Foods Complex





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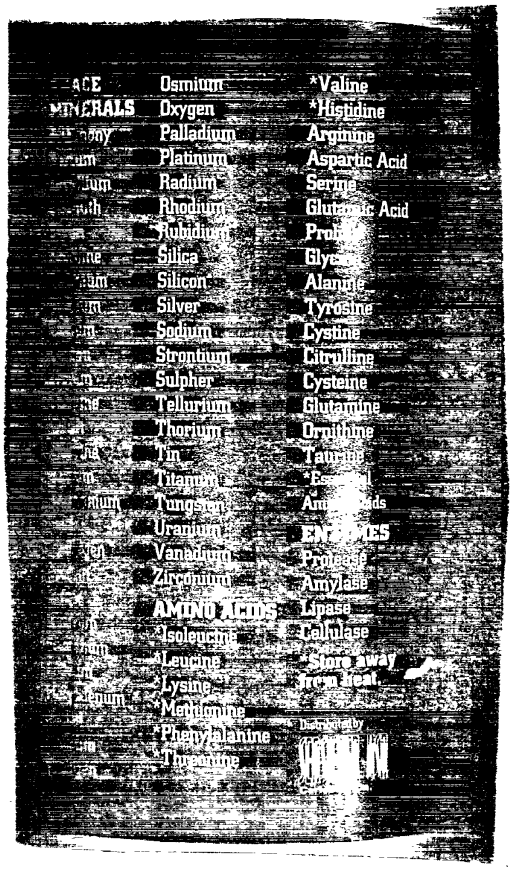
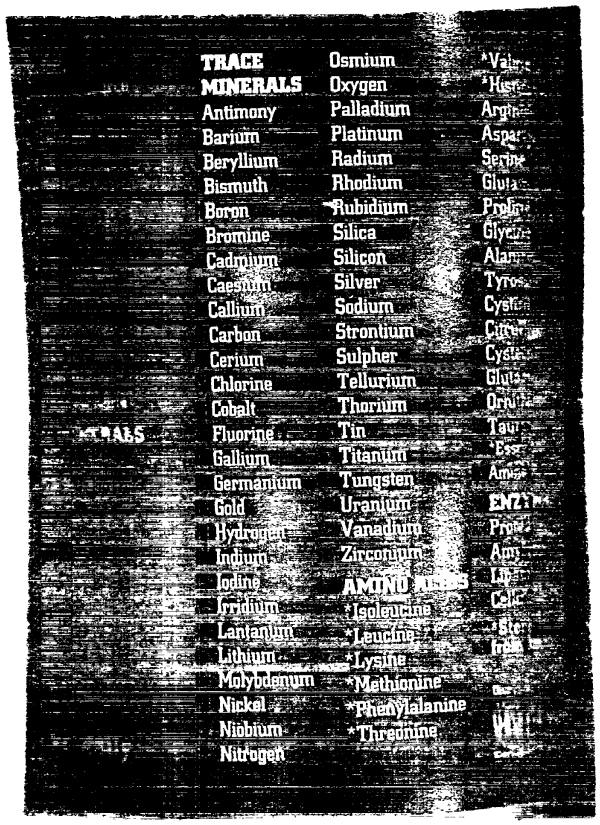
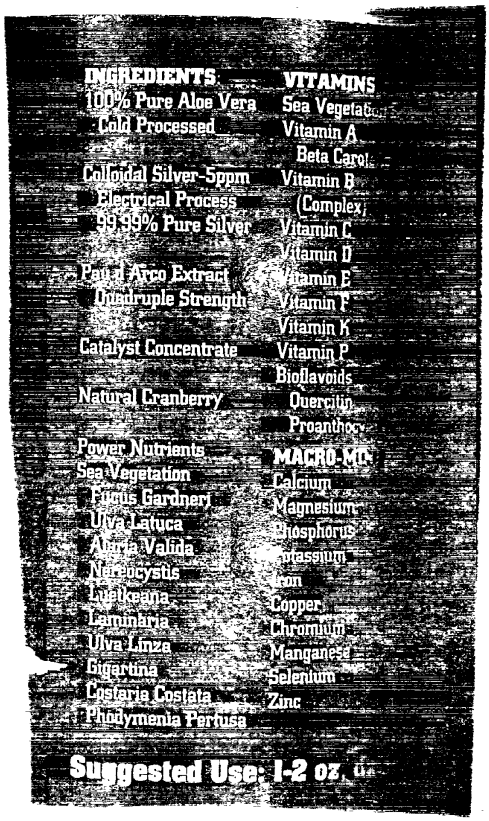


(48) "SeaSilver" - 32 Fl. Oz plastic bottle.

000032





Rejuvex

For Women — During and After Menopause

Special Nutritional Needs of Women in the Menopause Years

Estrogen has played a significant role in helping maintain a woman's health and [illegible] reproductive years. Now, with the onset of menopause, the production of estrogen is greatly diminished. Estrogen plays a role in the maintenance of strong bones and a healthy cardiovascular system. Reduced estrogen levels place women at higher risk for [illegible] bones and heart.

For many years health care professionals have been recommending calcium supplementation to women going through menopause because of the well-established fact that calcium is necessary to maintain strong bones and prevent osteoporosis. This is a well-founded recommendation. However, the most current nutritional research[1,2] now shows that calcium alone is not enough. *Rejuvex* is based upon the most current nutritional research conducted by noted researchers such as Mildred S. Seelig M.D., MPH, and Guy E. Abraham, M.D. Dr Seelig's research points to the fact that unless calcium and magnesium are present in a 2:1 ratio, then the effectiveness of calcium will be greatly diminished.[1]

A balanced diet is key to maintaining good health. Sometimes, because we don't always eat the foods which provide all the vitamins and minerals we need in the quantity that we need them, dietary supplementation is advisable. Although the recommended daily allowance (RDA) of magnesium is 400 mg/day, the dietary intake of magnesium by menopause-age American women is often as low as 100 mg daily. *Rejuvex* is a supplement formulated especially for the menopausal woman who may not be getting magnesium and other important vitamins and minerals in her daily diet. *Rejuvex* provides 500 mg of magnesium - 125% of the US RDA.

Satisfaction Guaranteed: If you are not satisfied with this Sunsource product, for a full refund of your purchase price (excluding shipping), mail us your original store receipt, the bar code from your package, and any unused portion of the product. Mail to:

Sunsource International, Inc.
Attn: Customer Service
535 Lipoa Parkway, Suite 110
Kihei, Maui HI 96753

Customer Service: If you have questions or comments about *Rejuvex*® or any other Sunsource® product, please contact our Customer Service Department at **800-666-6505**

Distributed by Sunsource International, Inc.
535 Lipoa Parkway, Suite 110, Kihei, Maui HI 96753

Printed on recycled paper with soy based inks

RXINS V7.0597.00685

"Rejuvex" (A9)
30 caplets
blister packs

000033

Nutrition Facts

Serving Size 1 tablet

Rejuvex

Amount Per Tablet	% Daily Value
Vitamin E (as d l Alpha Tocopherol Acetate) 30 IU	100 %
Thiamin HCL (Vitamin B_1) 2 mg	133 %
Riboflavin (Vitamin B_2) 2 mg	117 %
Niacin (Vitamin B_3) 10 mg	50 %
Vitamin B_6 (Pyridoxine HCL) 10 mg	500 %
Pantothenic Acid (d-Calcium Pantothenate) 10 mg	100 %
Magnesium (as Oxide) 500 mg	125 %
Selenium (as Sodium Selenate) 25 mcg	*
Manganese (as Sulfate) 2 mg	*

* Daily Value not established

Additional Ingredients: 200 mg Dong Quai root, raw glandular powders from bovine source 25 mg mammary, 19 mg ovary, 10 mg uterus, 10 mg adrenal, 5 mg pituitary, 3 mg Boron (as chelate, citrate and aspartate), microcrystalline cellulose (binder and disintegrant), croscarmellose sodium (disintegrant), colloidal silica (drying agent), stearic acid and magnesium stearate (lubricants)

Contains No: Sugar, starch, yeast, dairy, caffeine, preservatives, artificial colors, dyes or flavors

Suggested Use: As a dietary supplement, take one *Rejuvex* caplet daily, with a meal. For best results, do not take *Rejuvex* at the same time as a calcium supplement. Take *Rejuvex* in the morning and the calcium supplement at night.

Caution: Keep out of reach of children. Store in a dry place at controlled room temperature (59° 86°F).

Tamper Evident: Double safety sealed: outer tamper tape and inner bubble seal. Do not use if either seal or foil is lacking is missing or broken.

Rejuvex is not a replacement for any medically prescribed treatment. Do not discontinue the use of any medications, or alter the time at which you normally take them, when you add *Rejuvex* to your daily regimen. If you have any questions related to *Rejuvex* and any medications, consult with your health care professional.

Exercise and the Menopause Years

In combination with a balanced diet, low in sugar, salt and saturated fat, exercise is the single most important element necessary for optimal health. Exercise is particularly important for the woman in her menopause years as it helps to strengthen bones and stimulate new bone formation. It also helps to keep weight off and is a useful means for managing stress. Exercise will help to reduce the risk of osteoporosis and heart disease.

A balanced program of weight-bearing and aerobic exercise will help to increase endurance, muscle tone, strength and flexibility. Weight bearing exercise puts stress on the bones. When bones are not used they become soft and porous – a condition which can result in osteoporosis. Walking is a good weight-bearing exercise, whereas swimming is not because you are weightless in the water and your bones are not being stressed sufficiently to maintain and build new bone.

Here, as with diet, "balance" is the key. Over-exercise, just like under-exercise, can negatively affect the bones. Excessive exercise (non-stop for over 2 hours every day[5]) can result in a decrease in estrogen production which will interfere with calcium metabolism and result in bone loss. Consult with your health care practitioner to establish an exercise program that is right for you.

Footnotes

1 "Seelig MS. "Increased need for magnesium with the use of combined oestrogen and calcium for osteoporosis treatment", Magnesium Research (1990) 3 3 197 215

2 Abraham G, Grewal H "A total Dietary Program Emphasizing Magnesium instead of Calcium" Journal of Reproductive Medicine Vol 35 No 5 (1990) 503 507

3 Vallee BL "Metal and Enzyme Interactions: Correlation of Composition, Function and Structure" The Enzymes (1966) 225 270

4 Nielsen FH "Effect of Boron Depletion and Repletion on Calcium and Copper Status Indices in Humans Fed a Magnesium Low Diet" FASEB J 3 A760 (1989)
Nielsen FH, Hallbert DM, Gallagher SK, Hunt JR, Hunt CD, Johnson LK. Effects of Dietary Boron, Aluminum and Magnesium on Serum Alkaline Phosphatase, Calcium and Phosphorus and Plasma Cholesterol in Postmenopausal Women" Hurley LS, Keen CL, Lonnerdal B, Rucker RB (ed.) "Trace Elements in Man and Animals." VOL 6 New York Plenum (1988) 67

5 Gittleman AL "Super Nutrition for Menopause", New York, Simon and Schuster, (1993) 131

Vitamin B_1 & B_6: Magnesium, acting together with vitamins B_1 and B_6, is essential for the proper balance and functioning of the enzyme system.[1] Enzymes act as catalysts for the complex biochemical reactions that take place in the human body. A deficiency in these vitamins will negatively effect this delicate balance, thereby increasing the need for magnesium.

Vitamin E: Magnesium works closely with the anti-oxidant vitamin E to protect cells from damage by helping to maintain the strength and integrity of the cell wall. A diet which is deficient in this important nutrient increases the need for magnesium, but most importantly interrupts the delicate physiological balance necessary for the maintenance of health on the cellular level.

Selenium: Selenium is an essential trace mineral. "Essential" means that it is known to be essential for good health, though its exact nutritional role has not yet been firmly established.

Boron: Boron is a trace element that has been included in *Rejuvex* as an additional ingredient. In 1987, researcher Forest Nielsen, Ph.D., studied the effects of boron supplementation on post menopausal women. He found that through its relationship with vitamin D, boron reduces the loss of both calcium and magnesium and increases the blood levels of estradiol, the most active form of the estrogen hormone. The presence of this natural estrogen helps in maintaining the balance necessary for a healthy heart and strong bones.[4]

We have also included, in the formulation of *Rejuvex*, glandular powders and an herb that have been traditionally valued for women during and after menopause by cultures whose history dates back thousands of years.

Dong Quai (Radix Angelicae Sinensis): Herbalism, the foundation of traditional Chinese medicine, brings us Dong Quai. Centuries of traditional use of this safe and effective natural herb have shown that it may provide many health benefits for the mature woman.

Glandular Powders: Another form of traditional health care dating back thousands of years is glandular therapy. The freeze-dried glandular powders which are part of the *Rejuvex* formula come from a bovine (cow) source. Glandulars have been included because thousands of years of traditional use, substantiated by modern scientific research, indicates that glandulars provide nourishment to the body.

Questions and Answers

Q: Can I take a multi-vitamin along with *Rejuvex*?

A: Yes, *Rejuvex* is not a replacement for a multi-vitamin.

Q: Why is there no calcium in *Rejuvex*? I understand calcium supplementation is necessary for menopause aged women.

A: Calcium is important. However, when magnesium and calcium are taken together, they "compete" for absorption into the bone, and generally this practice results in an increased magnesium requirement. For maximum benefits from calcium and magnesium, it is best not to take them together.

Q: I would like to take a calcium supplement along with *Rejuvex* to help [illegible] of strong, healthy bones. How much calcium should I take and when should I take it?

A: Research indicates that calcium and magnesium should be taken in a 2:1 ratio. *Rejuvex* provides 500 mg of magnesium. American women often receive as little as 100 mg per day of magnesium from their daily diet, yielding a combined total of 600 mg. Therefore, 1200 mg of total calcium (from diet and supplements combined) would be the optimum amount of calcium. Take Rejuvex with breakfast or lunch, and for best results, take calcium at bedtime.

Q: [illegible]

A: Yes. *Rejuvex* helps to provide nutritional support to the menopausal woman.

Q: Is [illegible] replacement for estrogen replacement therapy?

A: *Rejuvex* is a natural dietary supplement. It is not estrogen therapy, and therefore is not a replacement for estrogen therapy. If you are wondering about *Rejuvex* as a natural alternative to any medically prescribed treatment, please discuss it with your physician.

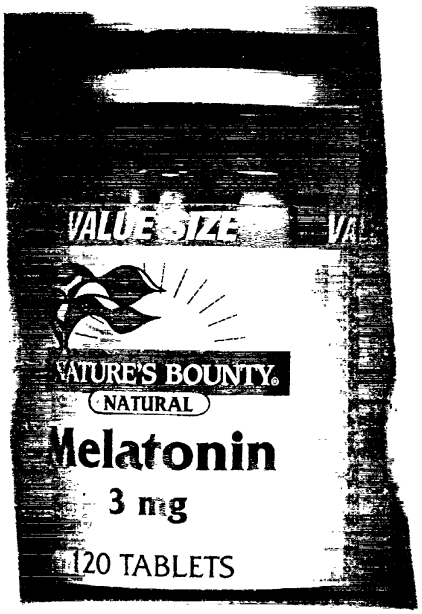
Q: [illegible]

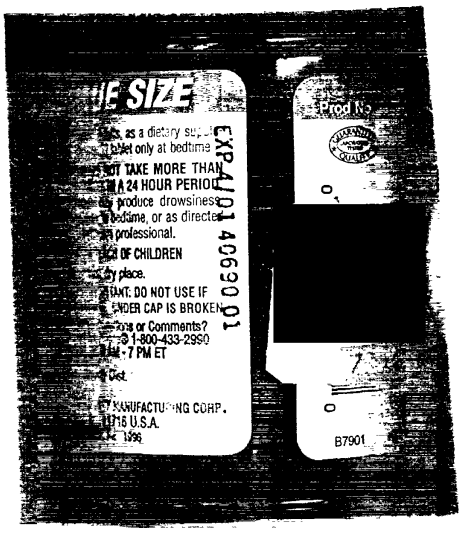
A: Yes. The nutritional needs of the woman experiencing surgical menopause are similar to those of the woman experiencing natural menopause.

Q: [illegible]

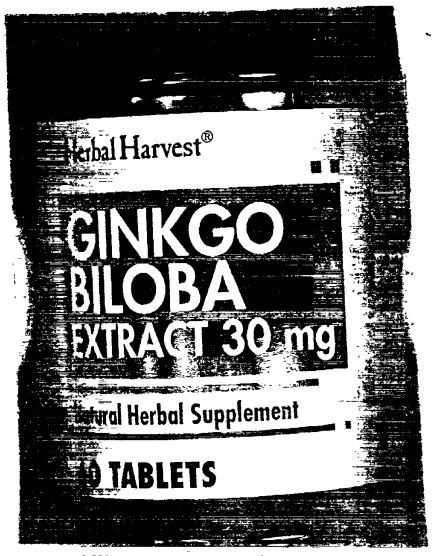
A: The freeze dried glandular powders in Rejuvex come from cows. They are subject to scrutiny by USDA licensed inspectors and must be certified as disease and contamination free and free of antibiotics, synthetic hormones and pesticide residues before they are allowed for use in pharmaceutical and nutritional products.

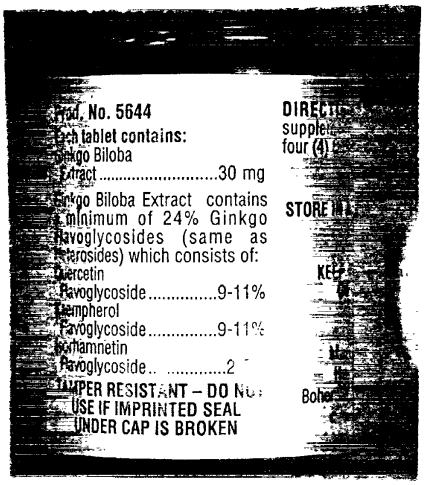
(49) Insert from package of "Rejuvex"

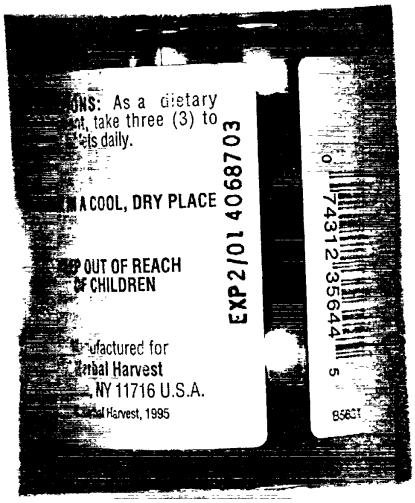




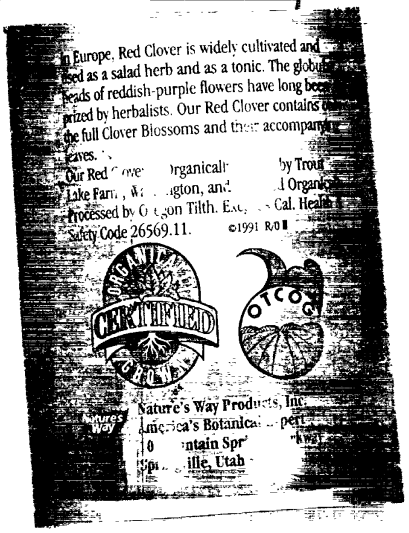
(50) "Melatonin" - 3mg - 120 tablets - plastic bottle.

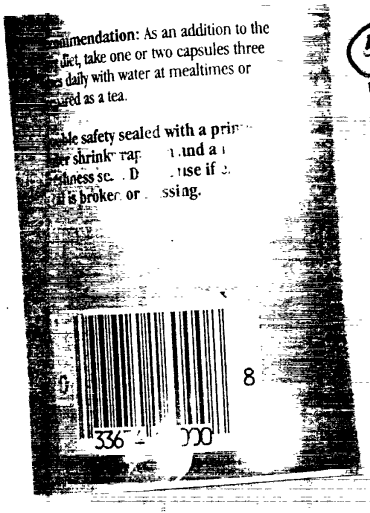






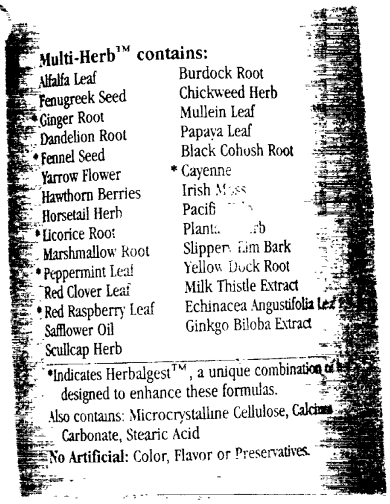
(51) "Ginkgo Biloba" - 30 mg - 60 tablets - plastic bottle

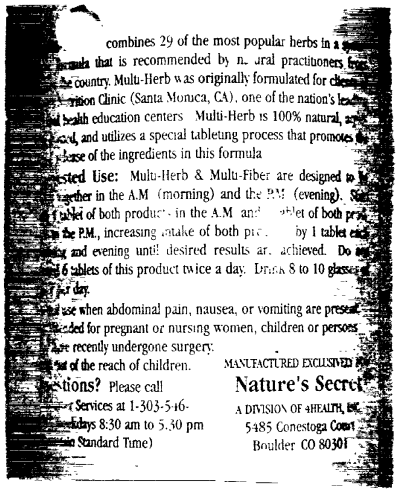




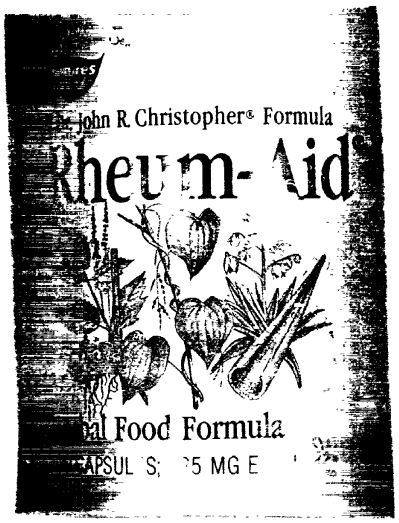
(52) "Red Clover" Blossom and Herb 100 caps 430 mg each plastic bottle

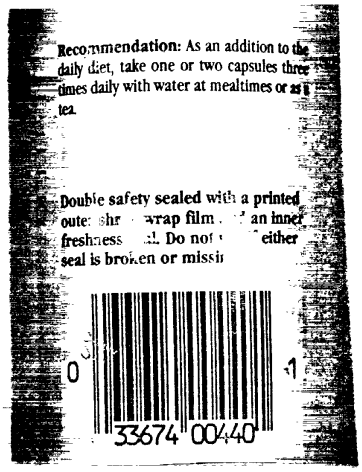
000035

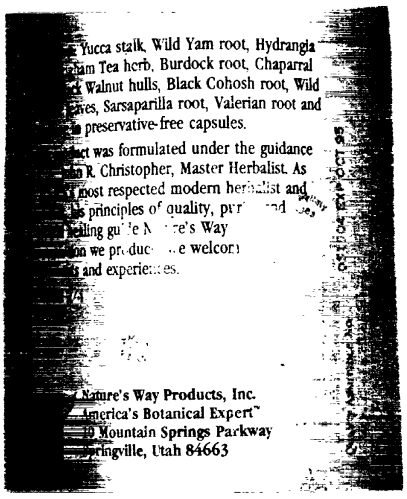




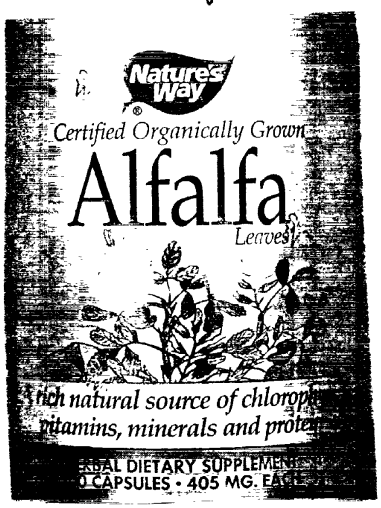
(53) "Multi-Herb" Herbal Dietary Supplement
120 Tabs / 980 mg each (plastic bottle)

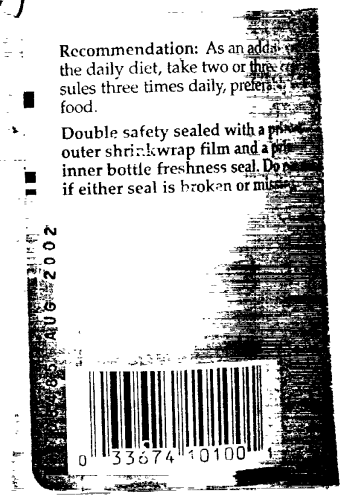


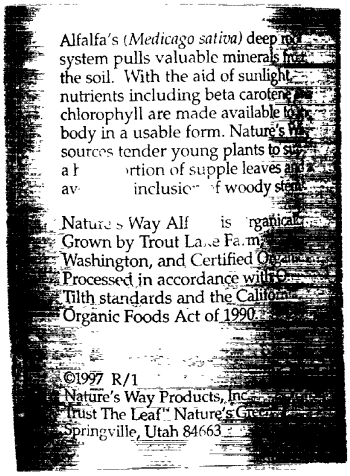




(54) "Rheum-Aid" Herbal Food Formula
100 caps / 425 mg each (plastic bottle)







(55) "Alfalfa" Leaves
100 caps / 405 mg each (plastic bottle)

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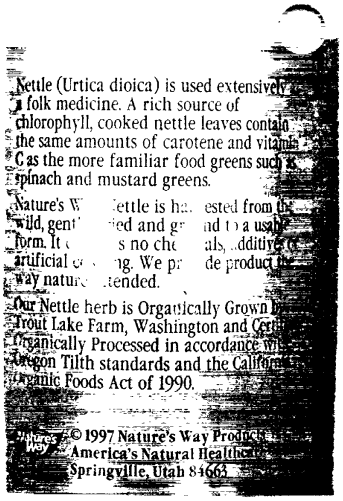
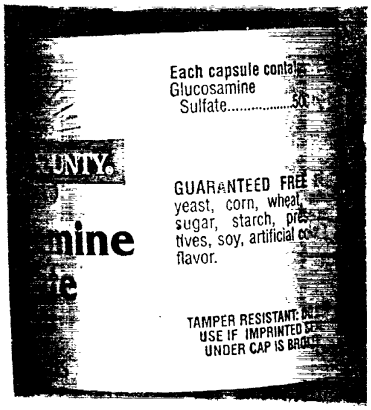
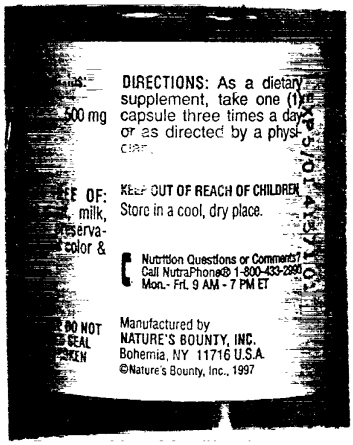
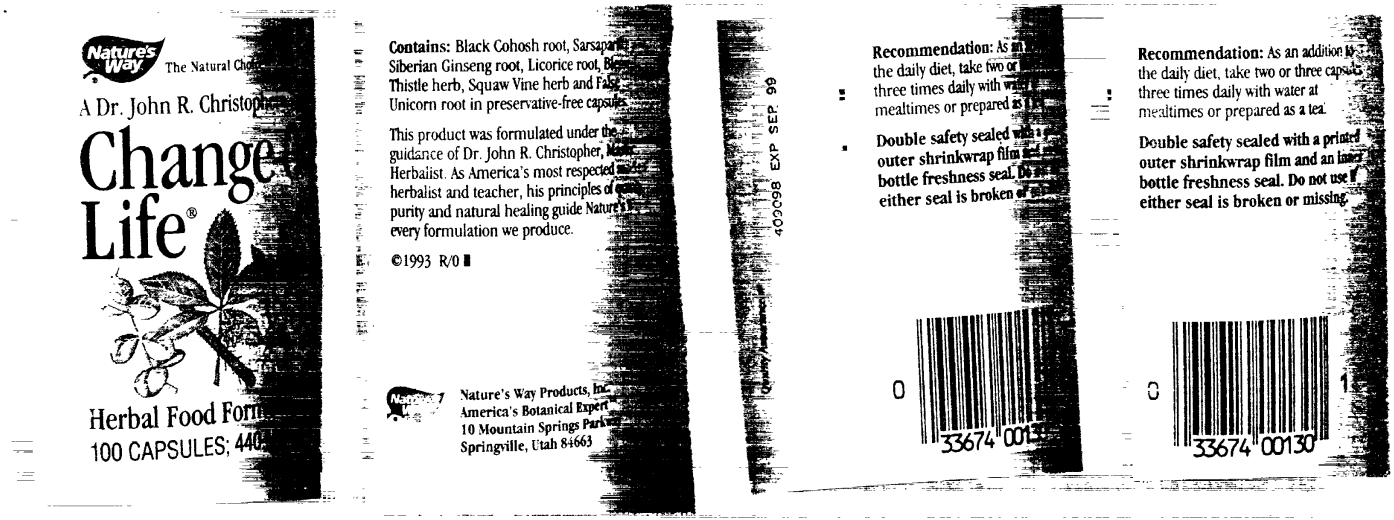


(56) "Nettle" Herb - 100 caps / 435 mg each plastic bottle





(57) "Glucosamine Sulfate" - 30 caps / 500 mg each (plastic bottle)



(58) "Change-O-Life" - 100 caps / 440 mg each plastic bottle

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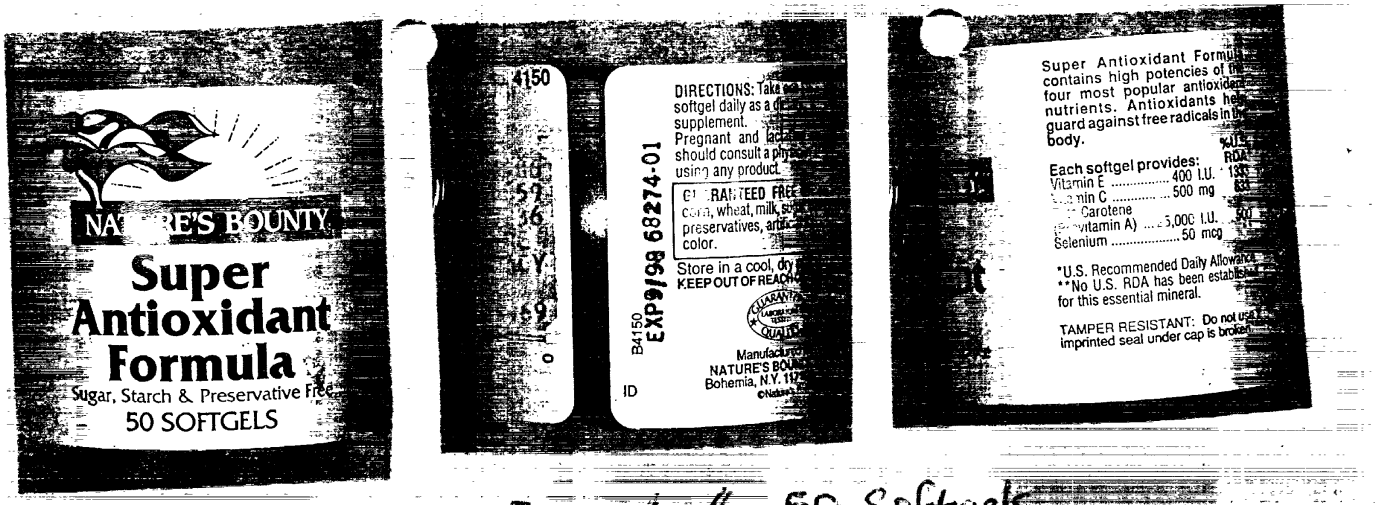
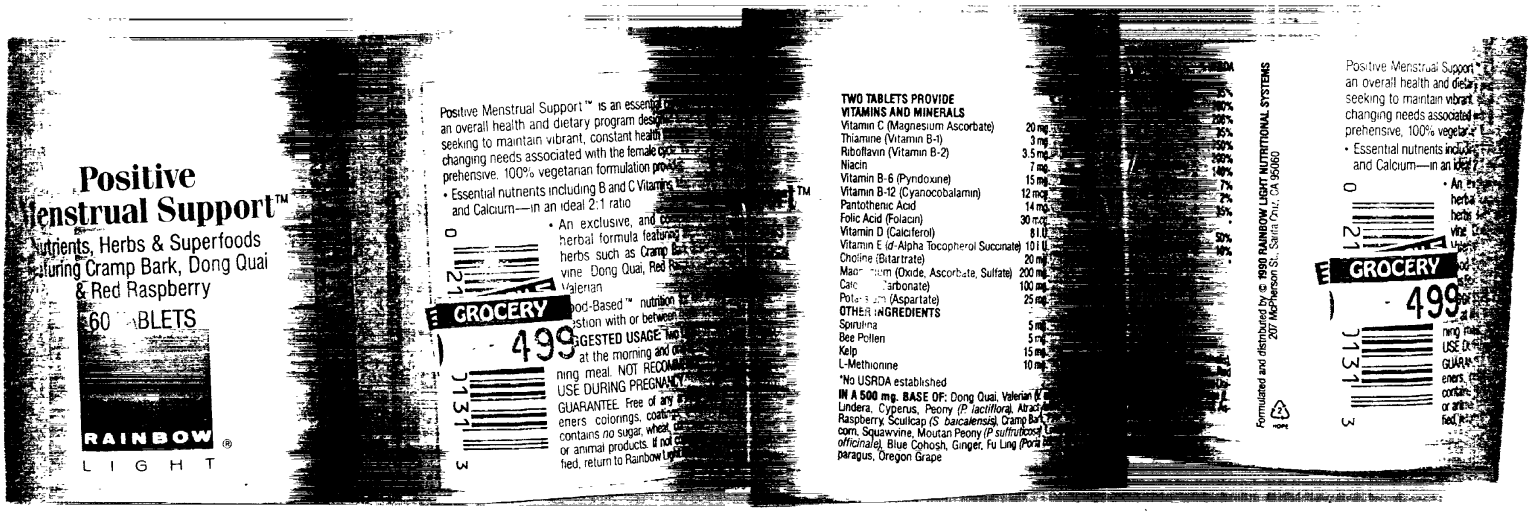
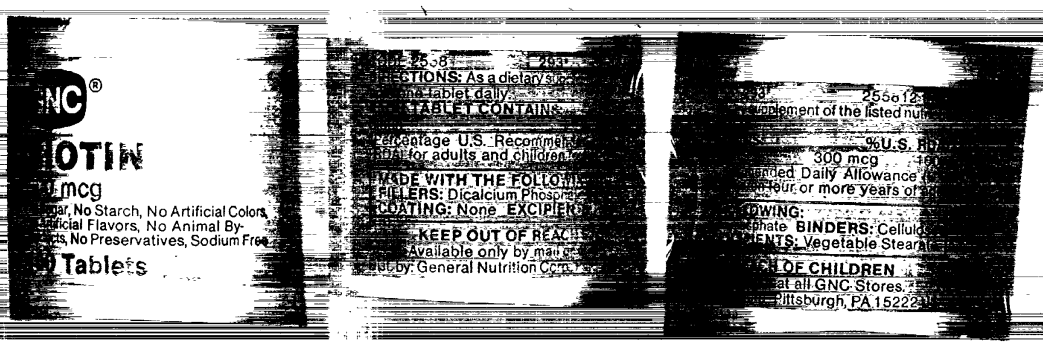


(59) "Super Antioxidant Formula" - 50 Softgels plastic bottle



(60) "Positive Menstrual Support" - 60 Tabs - plastic bottle

(61)
"AuraCacia SAGE"
Essential Oil
½ fl. oz.
glass bottle



(62)
"BIOTIN"

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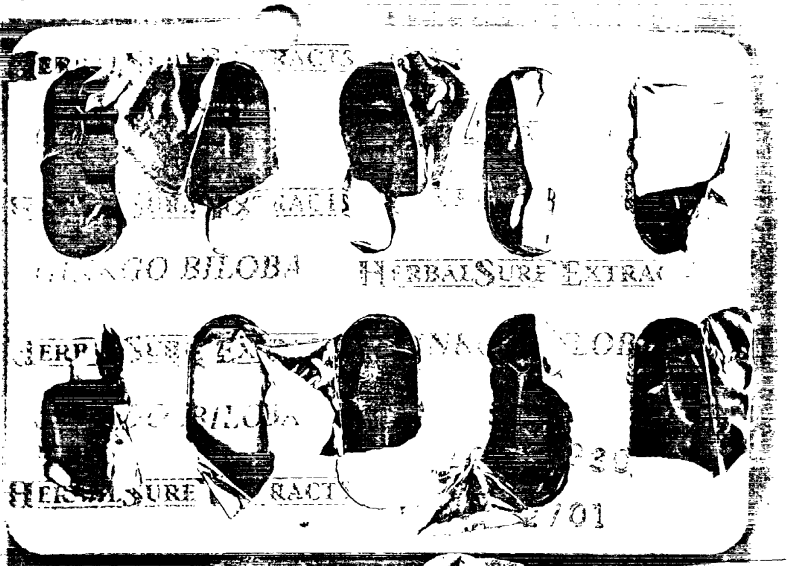
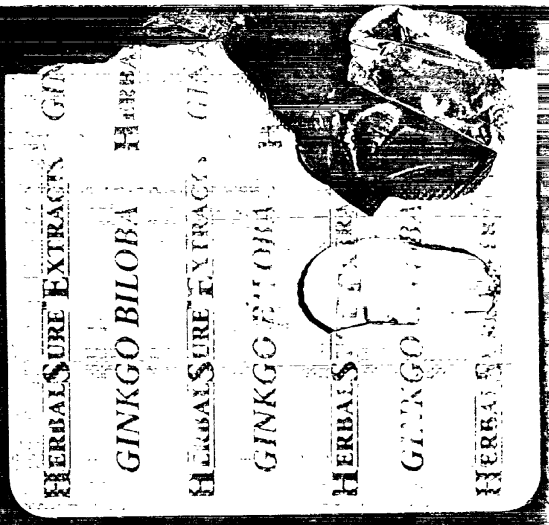
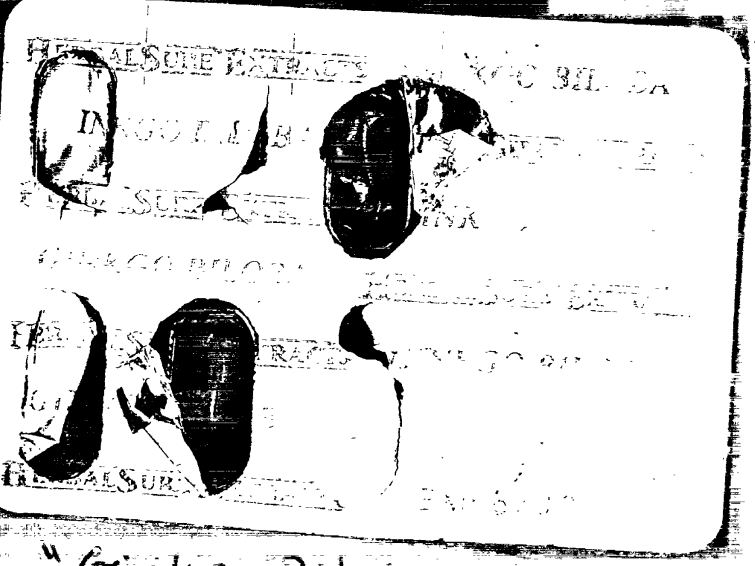
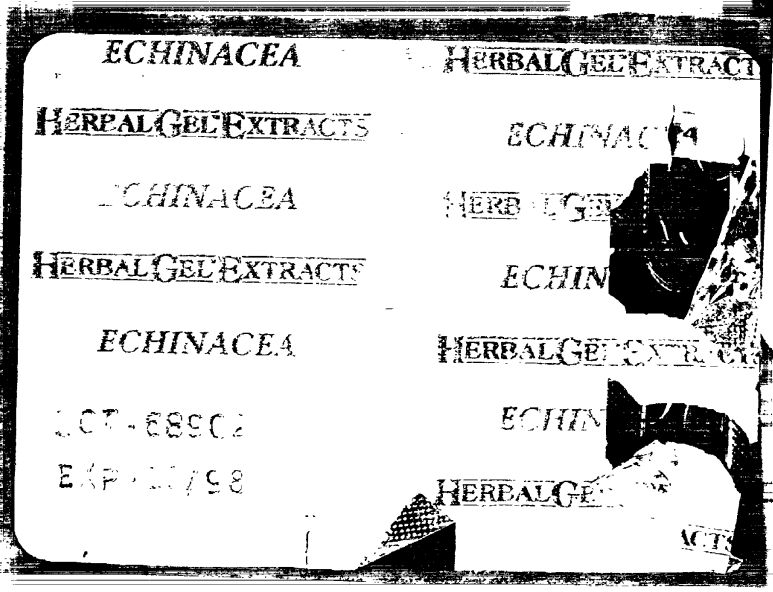
(03) "Ginsana" 100 mg Standardized Capsules





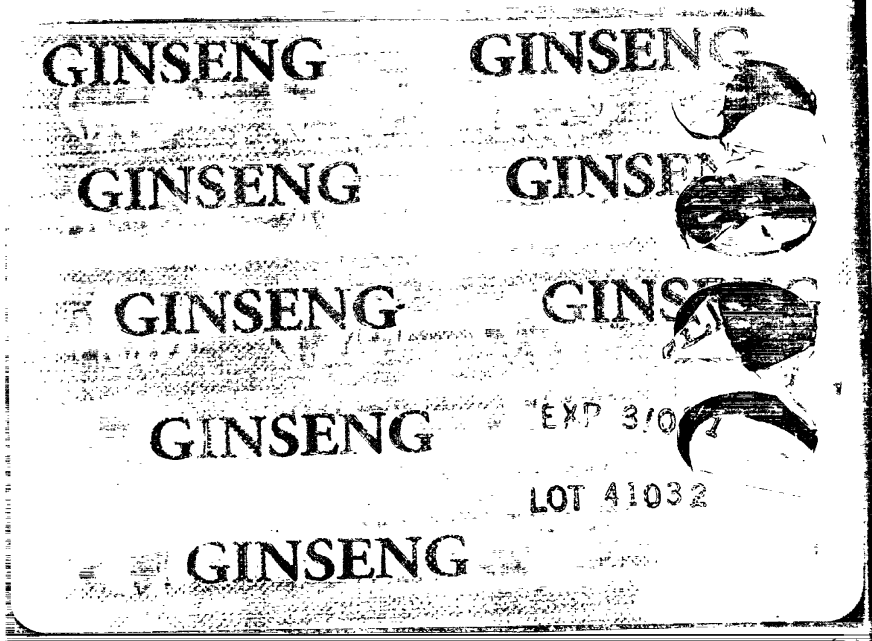


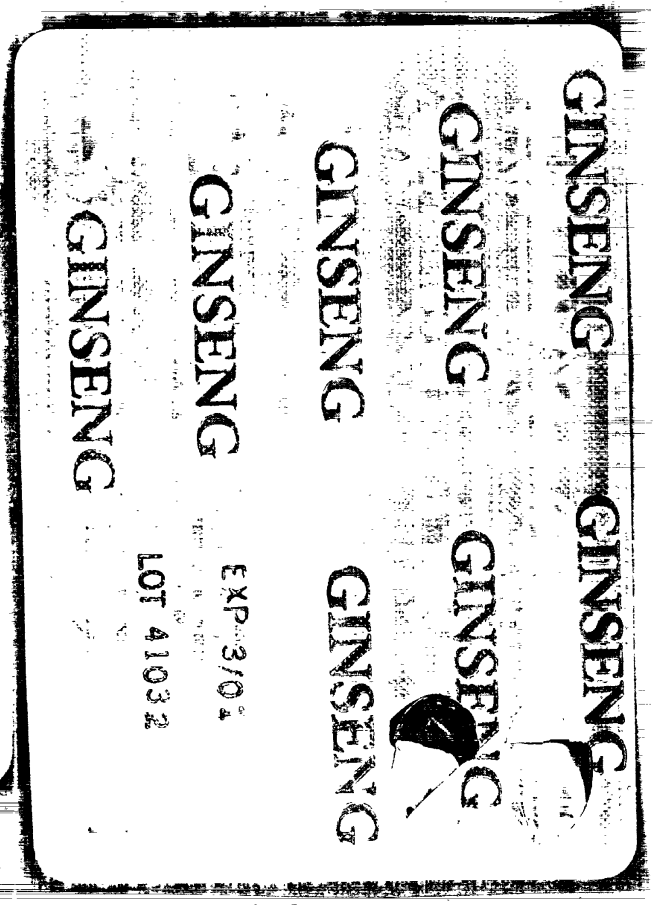
"Ginkgo Biloba"
(45)



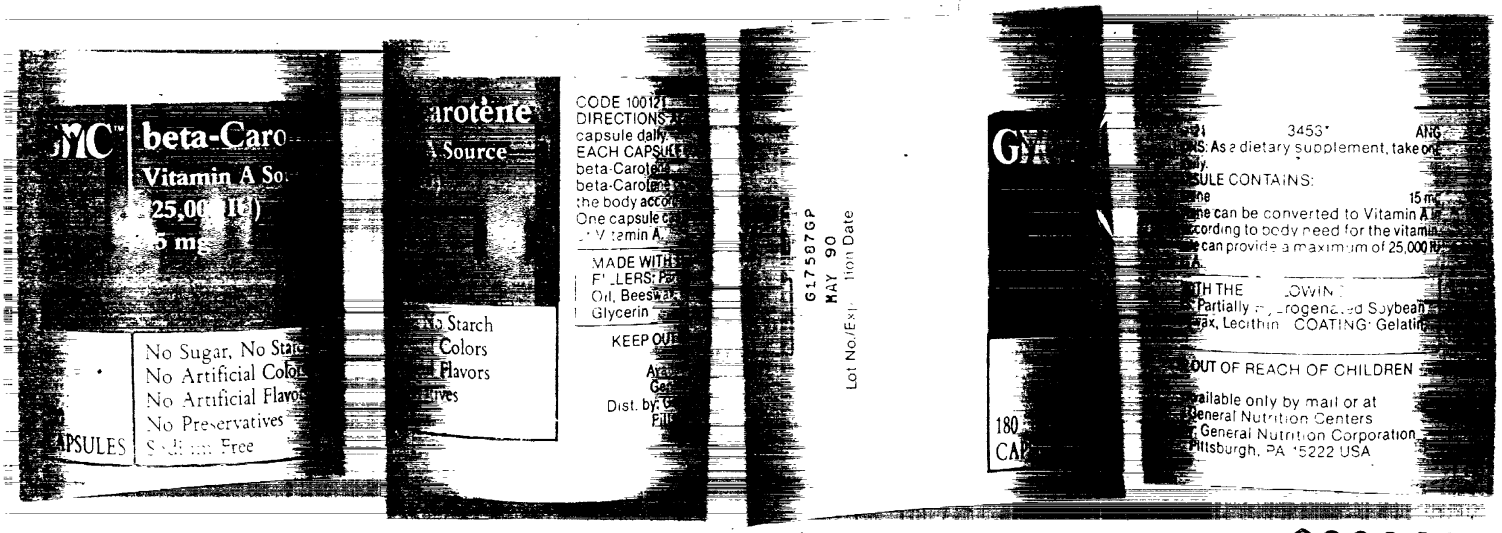
(4) "Echinacea"

(66) "Chlorella" A Green Micro Algae - 300 tabs - 200mg each plastic bottle





(67) "Ginseng" - blister packs



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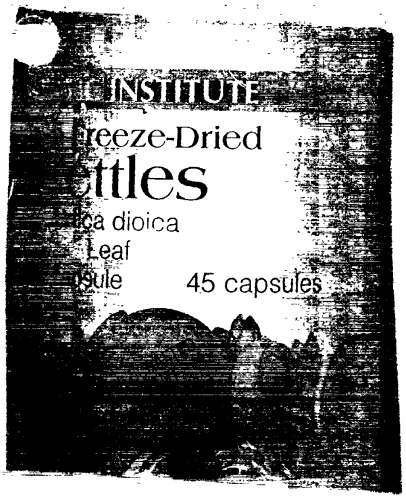
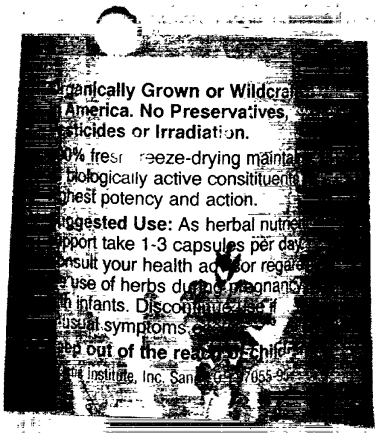
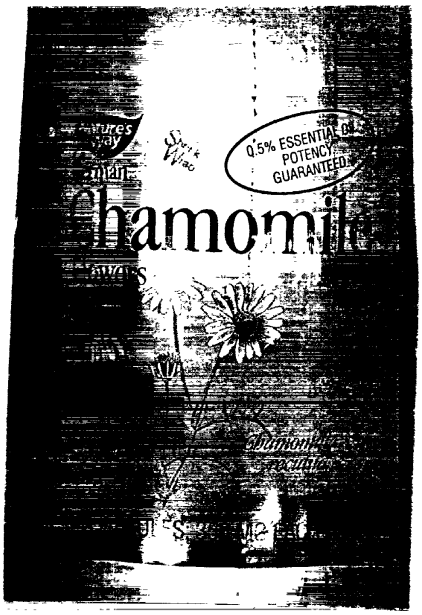
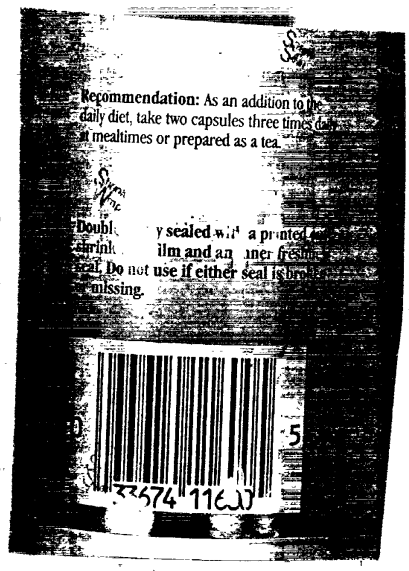
(68) "beta-Carotene" Vitamin A Source. 100 capsules

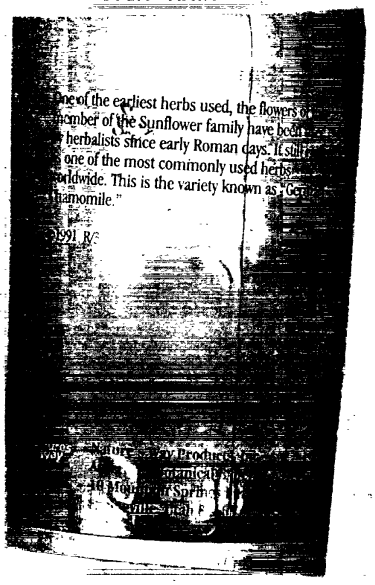




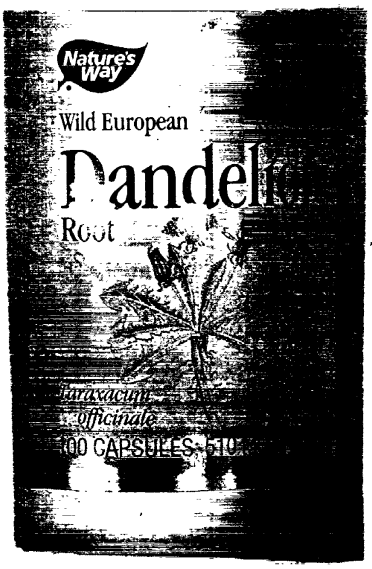
(69) "Nettles" Leaf - 45 capsules - 300 mg each plastic bottle

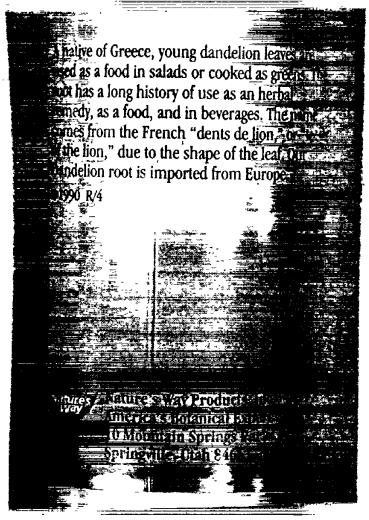


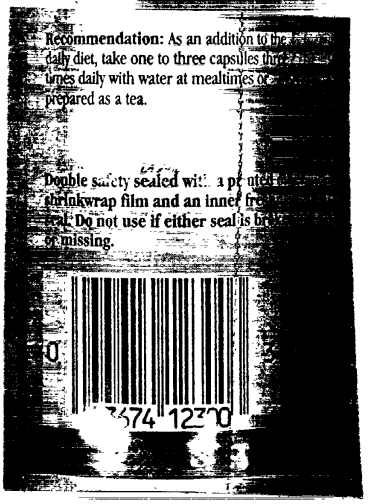




(70) "Chamomile" Flowers - capsules - 350 mg each plastic bottle







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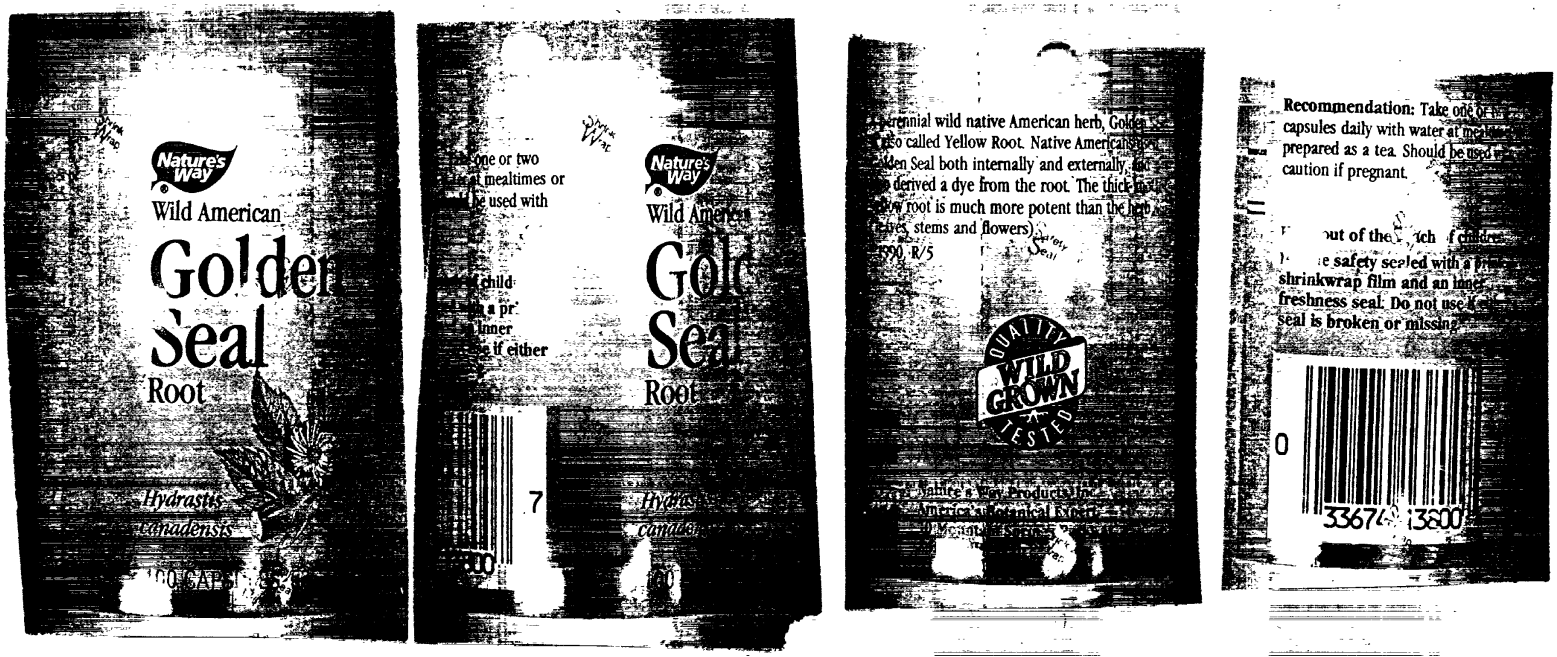
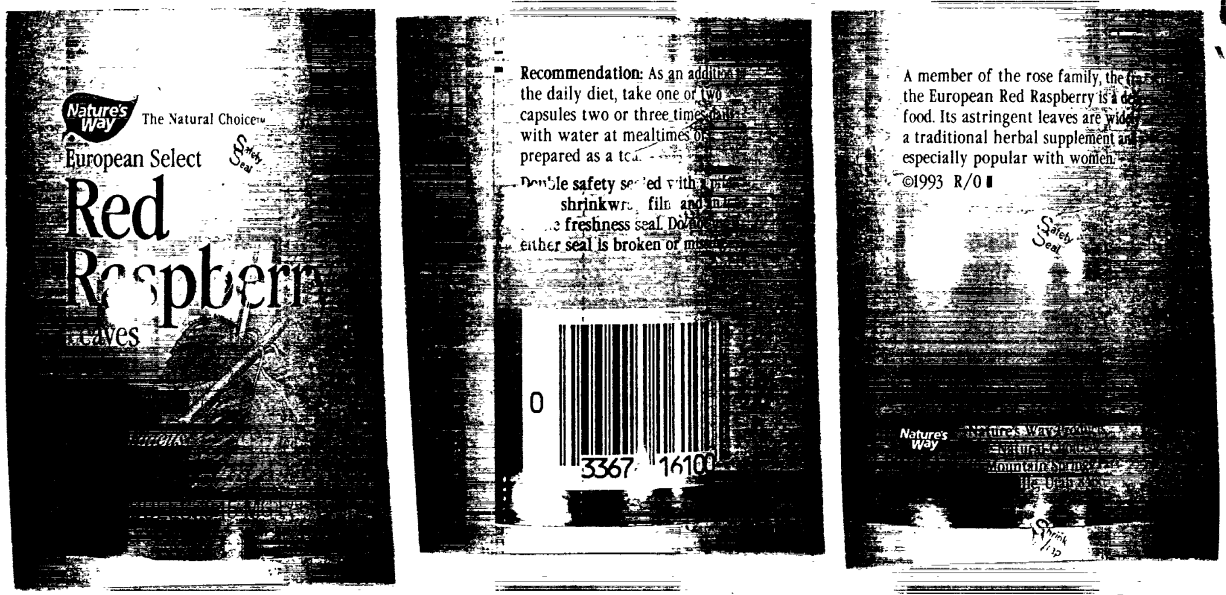
(71) "Dandelion" Root - 100 capsules - 510 mg each plastic bottle

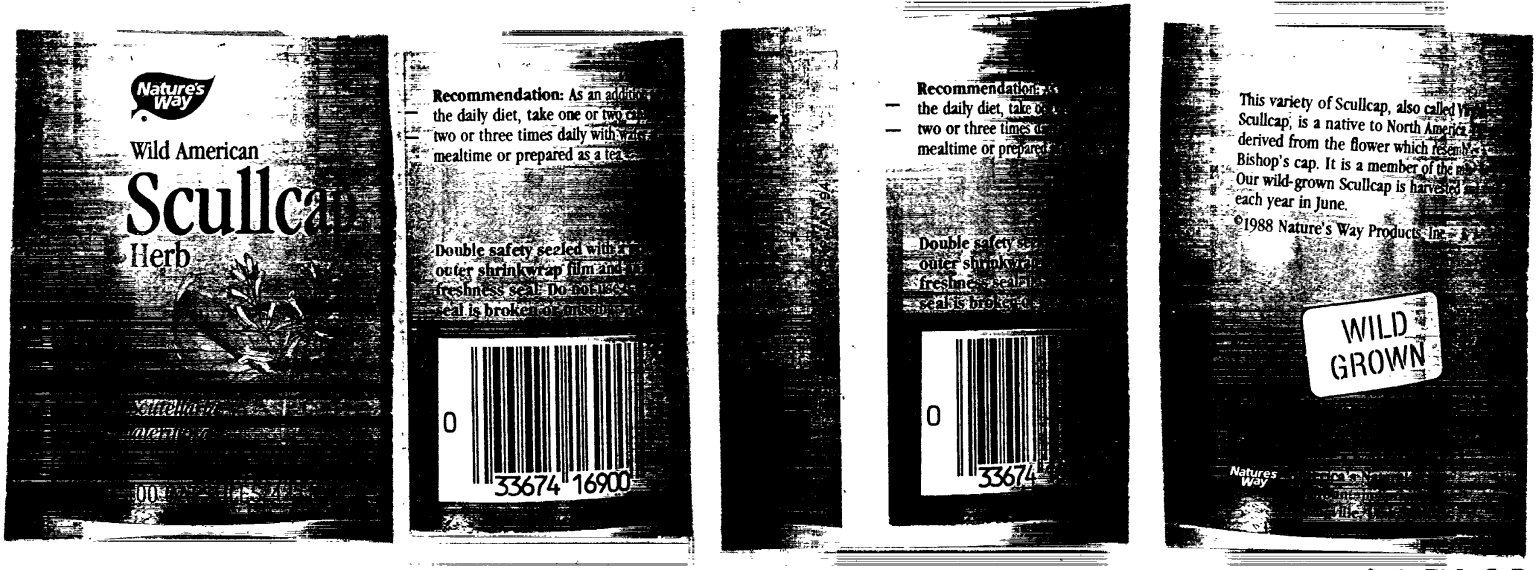


(72) "Golden Seal" Root - 100 capsules plastic bottle

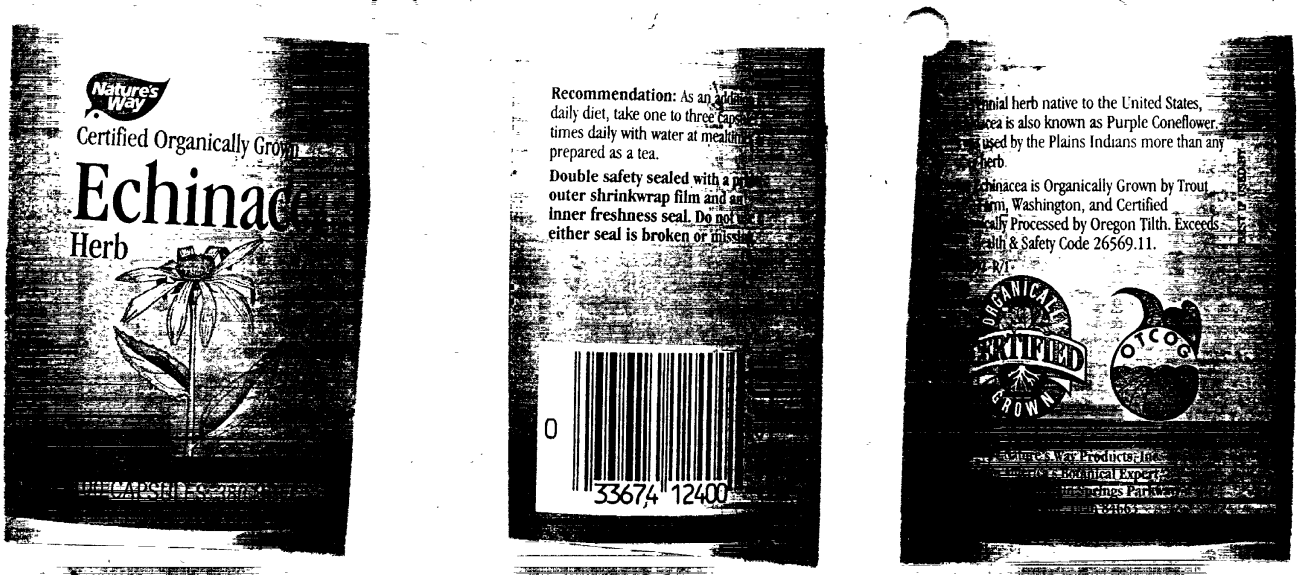
(~~73~~) (73)

"Red Raspberry" Leaves 100 capsules 345 mg each plastic bottle

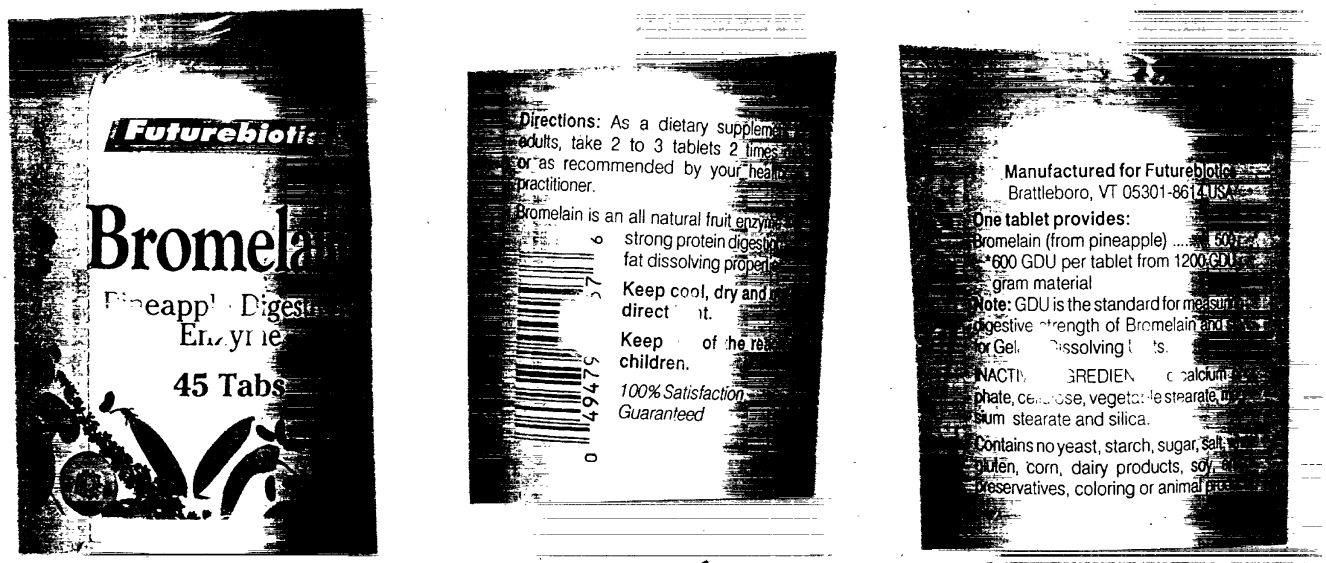




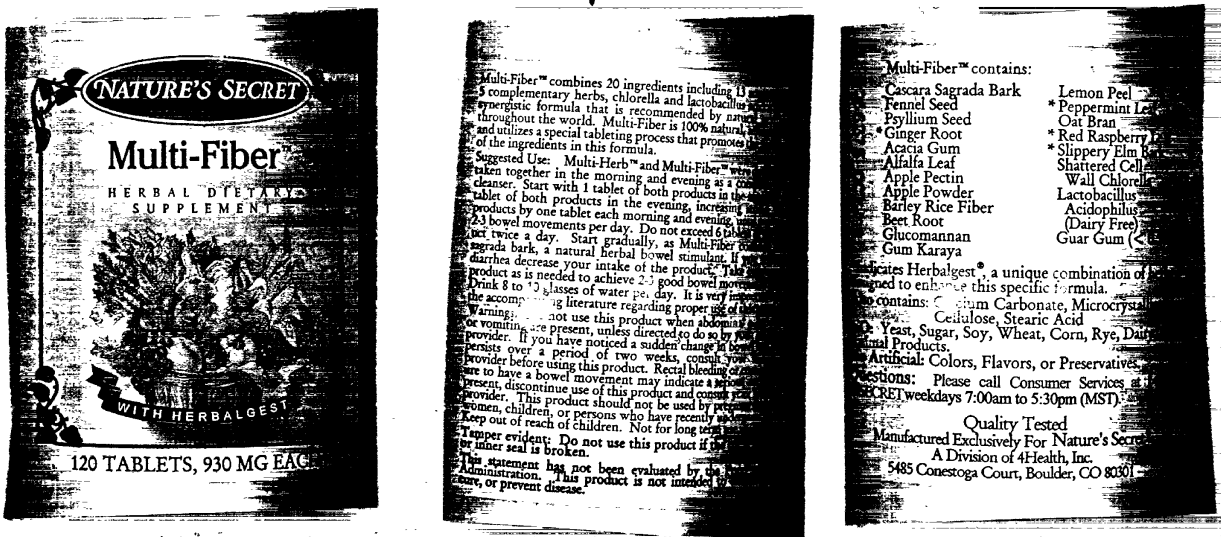
"Scullcap" Herb - 100 capsules - 425 mg each



(75) "Echinacea" Herb - 100 capsules - 380 mg each
plastic bottle



(76) "Bromelain" Pineapple Digestive Enzyme.
45 Tabs - plastic bottle



(77) "Multi-Fiber" Herbal Dietary Supplement
120 Tabs - 930 mg each - plastic bottle

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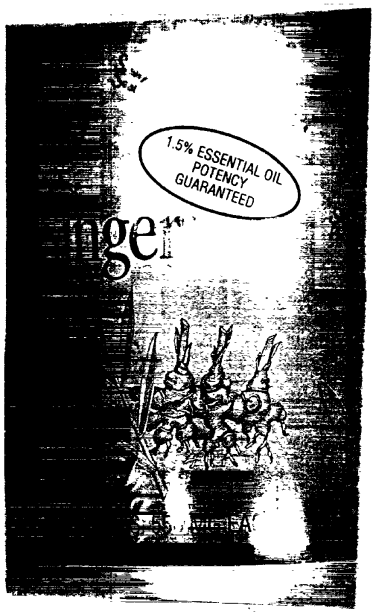
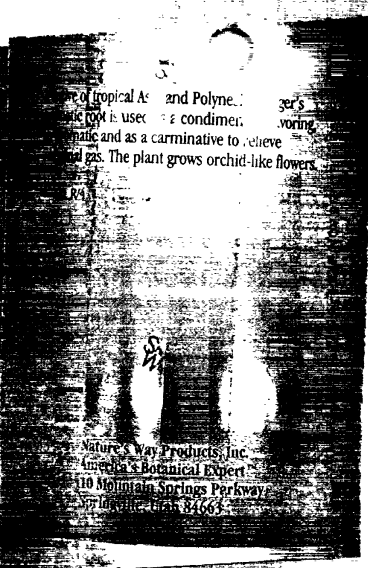
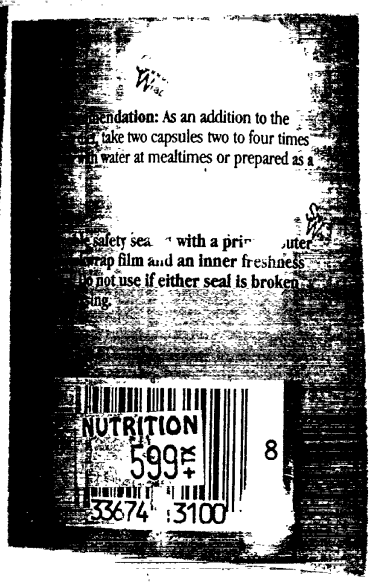
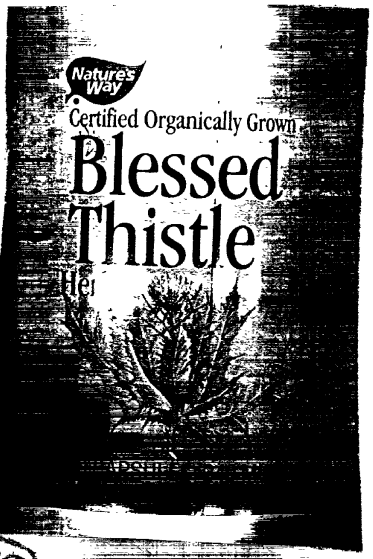
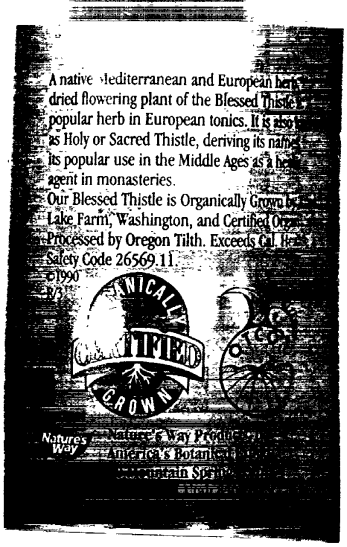


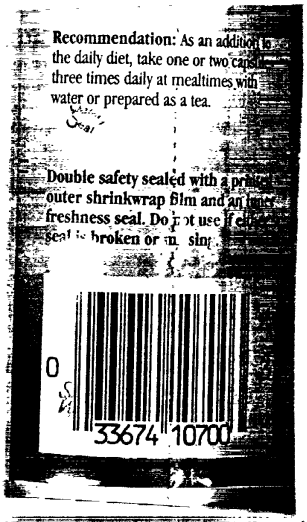




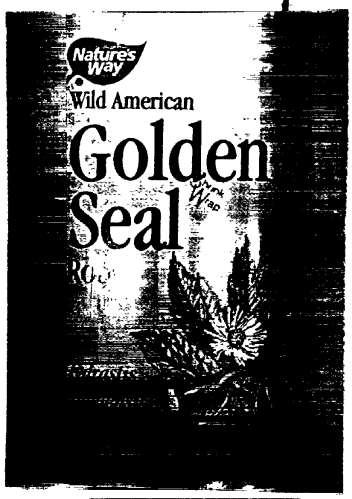
(78) "Chinese Ginger Root" - 100 capsules - 535mg each plastic bottle

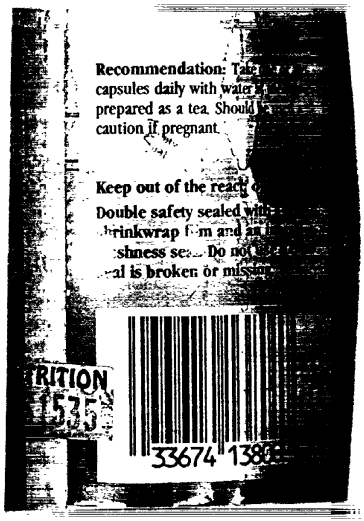


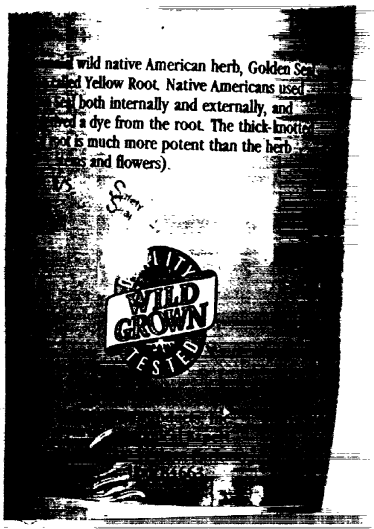




(79) "Blessed Thistle" Herb - 100 capsules - 535mg each plastic bottle







(80) "Wild American Golden Seal Root 100 capsules 535mg each plastic bottle

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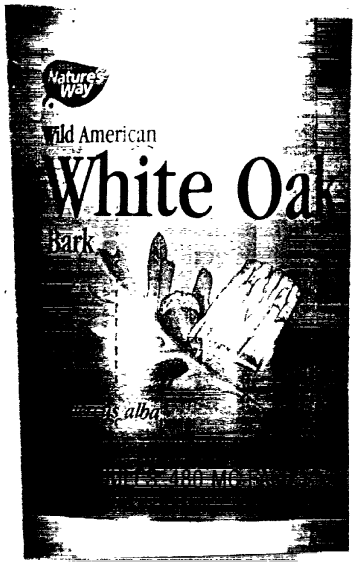

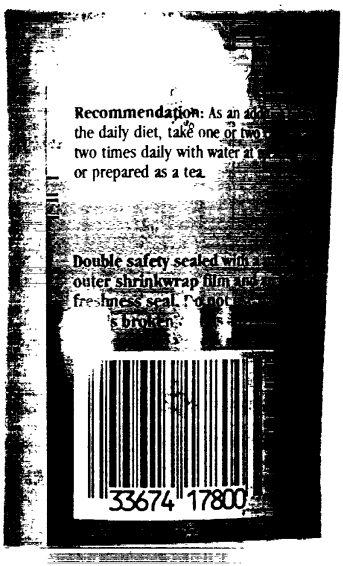

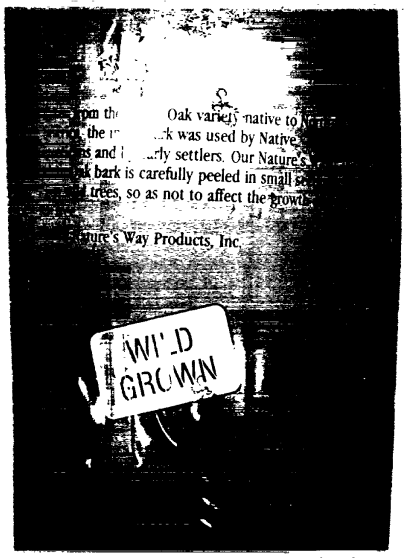

(81) "Wild American White Oak Bark."
Capsules - 480 mg each
plastic bottle

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